

UNITED STATES DEPARTMENT OF AGRICULTURE

**NATIONAL ADVISORY COMMITTEE ON MEAT AND  
POULTRY INSPECTION MEETING**

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## P R O C E E D I N G S

8:44 a.m.

## Recap

MS. SWACINA: Good morning. Glad to see almost everyone came back.

I understand that a lot of good work got done last night, just as there was yesterday, and I know some of you were here late. We appreciate that, and we're very much looking forward to hearing what went on and talking through those issues.

I did want to remind everyone, also, that we are going to try and fit in a discussion on the directive, the Salmonella Directive, and we want to try and fit that in right before lunch. So, I want to try and keep on schedule and even ahead of schedule, if that's possible, because I'm hoping at 11:30 that we can turn to that discussion, and I know we have a tight schedule today. I know people have planes to catch and so I will be kind of pushing you along, and I apologize in advance for that.

Okay. Everybody should have in front of them the draft documents from the subcommittee work last night, and I guess first up will be Mr. Mamminga from Subcommittee Number 1.

## Standing Subcommittee Number 1

MR. MAMMINGA: Well, thank you very much, Linda.

Our subcommittee was given the task of discussing the issue of the FSIS Workforce Roles and Structure, and I believe it's important to note that this is going to be an on-going work.

Last night, we were given a fairly narrow area to look at, but as I understand it, this will be work that is on-going over time and this committee will meet throughout the year in various ways to discuss other issues, but in this issue, we were given three questions primarily having to do with how FSIS disseminates their information, especially from their review findings, the reviews of the food safety systems correlation reviews, especially to their workforce, the industry, the states and other stakeholders, again looking at ways to address common problems and then there were some other questions after that.

We're very fortunate that we had a very good and diverse subcommittee membership. They all brought some different gift or area of expertise to it, and so we really had a very enjoyable session. We looked at a lot of things, and as indicated up here, the discussion points that we outlined were the goals of the reviews

were, first of all, to enhance establishment of food safety programs, and those of us that work with FSIS and work with our own systems, work with Bobby Palisano out of the Technical Service Center, know that very important part of HACCP over time is to enhance and improve systems. We all knew that these would be on-going goals when the HACCP rule was written.

We also like to increase inspection verification effectiveness of the FSIS personnel. In other words, are we -- it's a two-sided thing. How do we enhance the programs, and how do we enhance our effectiveness as inspection people to verify that the plans are what they say they are and do what they say?

So, we looked at some improvements and in an hour and a half's time, we had really quite a lot of discussion on a number of individual points, and we listed these points here as they came up that we discussed under improvements, to disseminate information to industry representatives who miss review meetings. These correlation meetings are held around the country. They are publicized and industry can go, but sometimes they don't for a variety of reasons, and so we would like to see that industry has an opportunity to find out what went on at those meetings and to share this information. So, in effect, better

advertise these meetings to industry, to compare districts and we're not talking client-by-client plant business here. We're talking about the findings, the results. What are we seeing that needs to be improved?

Another very important point we discussed was how do we improve the confidence that individuals have in the information that is disseminated by FSIS. You've got to have pretty high confidence level if you want people to take this up and move with it. To clarify the FSIS structure and chain of information transfer. The FSIS is a mighty industry, and it has many forms of communicating amongst itself and with its constituents, clarify this structure and the chain that the information goes to. To develop a computerized system that delivers scenarios. The IKE System was discussed as being a good thing. To better inform the plants that are not connected to trade associations, and Marty brought that up and it was a very excellent point, that, you know, not everybody belongs, and yet you have to reach everybody in our role and then FSIS's role.

To provide consistent information to inspectors and industry. I don't think I hardly need to explain why that is very essential. To clear up misunderstandings between scientific documentation and

validation. That's getting into some of the finer points of HACCP. To distribute generic summary of reviews. We thought that was very important. To create a listserv or a newsletter to answer inspector questions and share information in the field, to find out why information isn't known when deficiencies are found during reviews, and I thought that was a really important point that was brought up.

If we have deficiencies in systems, why? Is it because people don't know? Is it because they can't or because they won't? Is it because why? You can't solve a problem unless you know why. I think we all know how to deal with these issues, but you have to know the why before you can deal with it.

To improve management problems and to develop better accountability, to avoid a cookie-cutter approach. That's a nice way of saying not to be command and control. We don't have one checklist that everybody uses. We really believe in HACCP, that it is a system that is designed specifically for that plant and for that operation. So to provide the information in such a way that it isn't a one-size-fits-all information, and again another really innovative thought, FSIS as a guest commentator in trade association newsletters and other publications as a way

of getting out the word, the same word to all your constituents.

When we got to the point after discussing all of this, and these discussions went many different directions. We talked about a lot of things, and then we had to put those thoughts into an answer, a concise answer to three questions, and we had three members of our committee who seemed perfectly suitable to take our corporate thoughts and put them into an answer or a suggestion to FSIS, and so Marty Holmes with the North American Meat Processors Association, we asked him to address the first question that was put to our committee, having to do with how better can FSIS further disseminate our common review findings to the field force industry, to states and other stakeholders so we can work toward ways to address common problems.

Marty, why don't you go ahead and tell them what we came up with?

MR. HOLMES: I was given the task to take the -- after our lengthy conversation, to kind of capsule what we had discussed in answering Number 1 but did want to thank the subcommittee for everybody's participation last night and the agency for -- members of the agency who stayed to help us out.

The question was, what ideas does the

committee have on how we can further disseminate our common Food Safety Systems Correlation Team Findings to our field force, industry, the states, and other stakeholders, so we can work toward ways to address common problems.

We thought that, you know, I'll just kind of read through this, HACCP was intended to be a continuously-changing and improvement process. The committee feels there is valuable information to be shared through multiple vehicles and forums. Food safety systems correlation team meetings with industry following their findings do not reach everyone that could use them. Information should be consistently shared, and we kind of went through some ideas of, okay, everybody receives information different ways. Some people read the newspaper in the morning. Some people go to their Internet webpage. Some people listen to the radio. Some people watch tv. So, it's kind of like, okay, let's -- what all vehicles do we have to disseminate that information to the people so that they can hear it the way that they like to get information.

One idea was that if the IIC is supposed to sit down with the plant personnel on a weekly basis, maybe the agency could create an e-mail for the

inspector-in-charge every week that goes through various scenarios that play out, okay, in this situation, here -- and they may not apply to that plant for that week, maybe it's a slaughter information and, you know, here's a processing IIC that -- and so forth.

Maybe they can -- you could actually have various scenarios and if you're in this kind of plant, if you're in a poultry plant, here's your scenario to share. If you're in a slaughter plant, here's the scenario you share that week or whatever. The inspector prints it out and then sits down with the plant personnel to talk through it, and then also, the idea of -- and that was on a weekly basis.

As it relates specifically to the food safety systems correlation team meetings and Mike's comment that not everybody attends those or is able to attend them or they're not publicized enough in advance for people to get there, maybe that information could be put together in a concise format and put on FSIS website, shared through AFDO, through the HACCP Alliance. You know, we have this tremendous network through the small plant HACCP network that was developed as HACCP was being implemented. We could send that information through that network so it gets to all the plants that are not members of various trade

associations.

Obviously the trade associations would love to have that information to share with their membership and put in their newsletters and their different forms of communication. Certainly the trade publications would certainly be interested in having a role in that, whether it be as one of the things mentioned in our train of thought part at the beginning, which was guest articles in various trade publications.

The IKE System, Interactive Knowledge Exchange System, that the agency has available to them, you know, you have an inspector and every IIC has his own laptop now. So, you know, the vehicles are there to communicate this information, and we've got, you know, all the trade associations, everybody's electronically connected now. So, it seems like, you know, the cost to put that stuff together is minimal because we've got so much, you know, ease of communicating it out.

But a couple thoughts that we wanted to make sure we were careful as we went through this, that, yes, when we find areas that need to be improved and enhanced because somebody's doing it but they're not documenting it properly, they're not signing something off properly or they're not doing the things they need

to do, we just want to make sure that the inspector doesn't think that one plant's information is insufficient because it's not exactly the same as the one down the street in the same circuit, and so we just wanted to make sure that we realize that HACCP is not a cookie-cutter, hey, here's, you know, that's why we had these draft HACCP plans. They didn't work for everybody. This was just to give you some feel, some concept of what the agency was looking for and what the industry was looking for to give you kind of a barometer. So, just to be careful not to have inspectors thinking one's not sufficient because it's not exactly like another plant in his circuit.

Both industry and the agency need to be clear about how much and what kind of supporting documentation is needed. We find that a plant may be going along fine with the documentation or with his supporting documentation. A relief inspector comes in and says, well, that's not sufficient, and, you know, it's just kind of like -- it just adds confusion. So, there needs to be clear information there.

Go to the next question.

MR. MAMMINGA: Thanks, Marty.

The next question that was presented to us, we asked Michael Govro from the Oregon Department of

Agriculture to give our committee a perspective on that.

So, Mike?

MR. GOVRO: Okay. That question was what suggestions does the committee have for additional ways we can utilize the findings of the FSSCs to enhance the effectiveness of the field workforce, and we suggested that the agency could add a component to the review process to determine why the deficiencies exist.

It seemed that there was an assumption made, perhaps it's more than an assumption, but it says that the inspections are about finding areas in which inspection personnel and industry officials need further information and awareness. We thought that there may be some other problems that also contribute to a lack of compliance or a lack of following the correct procedures by the FSIS field personnel.

If it is found that the problem is that the plant and FSIS field personnel do not have enough information, this component could help determine why the information is not getting through and how to correct that problem.

For instance, there may be problems with information needing to be printed in other languages. It may be that it's not presented simply and clearly

enough. I think if you added a component to find out why it's not being followed and it is an information problem, you should be able to zero in on what you need to do to correct it.

Also, I think it would be important to simply ask the people who are involved with those deficiencies, if it is an information distribution problem, how they would like to receive the information. What would be better? Perhaps you could do some focuses or something to collect that information.

However, there may be some other problems that contribute to the deficiencies, such as poor management or problems with the enforcement system. One of the things that was mentioned in the meeting is that there may still be FSIS employees or plant managers and workers who have not made what was referred to as the paradigm shift away from command and control and completely to HACCP, and there may be a problem there that needs to be addressed through the management of the agency to get people to actually move more towards a HACCP system and away from the command and control.

One of the things that was mentioned in here as one of the deficiencies was that the plant personnel

are maintaining but not reviewing the records, and we all agreed that probably those personnel know that they are in fact supposed to review the records and that does not represent a lack of information on the part of those people and that may be something to do with enforcement, where the penalties for not complying with the procedures are not appropriate, and you may be able to look at that as well.

That's all.

MR. MAMMINGA: Thanks, Mike.

The third question we asked Catherine Logue from North Dakota State University to answer as being a very appropriate person to address this.

So, Catherine?

MS. LOGUE: Good morning.

Really, the aspect that I looked at to answer this question is what does the committee believe the findings of the FSSC may tell us about the make-up of our field workforce, and here, I kind of looked at it from the point of view that -- and if you go back to the statement, they said that they found there were shortcomings found related to the HACCP plan design and supporting data.

So, I began to kind of think about it along the lines of, well, if there are problems with the

HACCP plans, are there skill gaps? If so, why are these happening? And you need to look at it from the point of view that you need to start hiring individuals with the skills to address these issues that can actually fill these gaps, and one of the ways to do this would be to recommend at the plant level that they hire individuals with stronger backgrounds and more qualified individuals to do these kind of jobs, and we're talking things like certificate or diploma levels and beyond high school education and in some kind of food safety/food science or some kind of a background that will give them that.

The same thing could actually apply at the FSIS levels with the lowest ranks of inspectors, that a lot of them get hired with a high school education and they get some kind of training, possibly making them go back to school or getting some kind of an education where they get some kind of professional certificate with a degree of course work out of it, and it may give them an additional skill and a better advantage so that they'll actually get to see the bigger picture here.

One of the ways to do this is either FSIS goes ahead and starts sending these people to recognized institutions or they set up something internally in house in association with other

institutions, you know, form some kind of a joint thing, a bit like what the FDA is doing, and they've got this professional thing coming on board right now.

So, maybe FSIS would like to think along those lines.

As I said, that's the low-level inspectors and giving them this broader picture, and then when you've got these CSOs, you need to hire them at kind of a slightly higher level. In other words, make it that they can't come in unless they've already got a degree.

You hiring them at an already-qualified degree level, either degree or master's level, and then you've got a broader picture and you've got someone with a bigger background to handle these kind of things, and they definitely have a better, you know, quality of skills, and this is the way to go for the future, so it's how you can address these gaps as they turn up, and, you know, it makes the whole system more efficient.

That's all I've got to say.

MR. MAMMINGA: Well, again, we covered a lot of ground in an hour and a half before we put pencil to paper, and this is preliminary work on a pretty broad important subject. So this is what we offer for the committee's consideration.

Thank you.

MS. SWACINA: Thank you.

Is there a comment from the committee?

(No response)

MS. SWACINA: So, we can accept this report as it stands. I appreciate the cooperation in moving ahead. Thank you.

MR. NEAL: Very good job, everybody.

MS. SWACINA: Okay. Well, let's go ahead and move on then to the Standing Subcommittee Number 2, which is Mr. Link.

Standing Subcommittee Number 2

MR. LINK: Our subcommittee, last night, took on the challenge of talking about new technologies and specifically trying to figure out what incentives USDA could offer, I guess, to promote the use of new technologies and what incentives would foster technology partnerships among USDA, industry, academia and etc.

We had a great group last night, and I want to thank the subcommittee and also the FSIS folks who helped us out last night to kind of work through this issue. We did have some -- we were fortunate to have at least one technology provider in our group out sitting on the outer rim, if you will, that offered some insight as well.

So, when we first started going through this

issue, I guess the first thing we struggled with was both of these questions kind of looked the same to us.

So, we kind of took them as one big issue as to how we could promote the use of technology and technology partnerships.

A lot of brainstorming going on primarily looking at what incentives might be out there, what barriers currently exist that we might need to overcome, and it was suggested that possibly the first thing that should happen, maybe USDA should have a survey and survey the FSIS staff, survey the industry, survey other stakeholders to identify what those barriers are, so that we can overcome those, and also to try to identify what incentives might exist or could be developed to help innovate and develop some of these new technologies, and we came up with some ideas, and we kind of bounced it around the room, but none of us are really technology providers and couldn't really speak to some of the issues that they face when they're trying to get some of the new technologies or new food additives or things of that sort approved.

But so we did list a few ideas that we came up with, and the first was the approval process, and I know it's getting better. I know FSIS is working through the revision of the 10,700.1 directive, but

still somewhat cumbersome or maybe some people just don't even know there's a single point of entry now, and so to get that information out and maybe revise or improve the approval process would be a benefit.

I think I brought up yesterday the FDA/FSIS MOU with regards to new technology or particularly with food ingredients, food additives. There seems to be somewhat of a disconnect with information transfer between FDA and FSIS and maybe if there were a single point that we could get to, if FDA has got -- if they approve a food additive, do we need to go through FSIS, also? Is there a way to make that process better?

Labeling disincentives. We had a conversation, and I guess it could go either way. You could have labeling incentives to allow a company to promote the fact that they're doing certain things, but, also, we're looking at disincentives where using the technology or using the particular processing aid would require some labeling that is hard to understand by consumers and it appears to be a disincentive rather than an incentive.

Use of indicator organisms. We had talked about doing research and you can do research in laboratories and use pathogens and things of that sort, but when you get into the processing environment, to

find out how it really works on the plant floor, using pathogens can be a problem. So, we talked about is there a way we can use indicator organisms on the plant floor to kind of move through some testing that needs to be done? Obviously the expense of the technology is a barrier. Some of the stuff's extremely expensive and some of the smaller plants can't get into the market.

There was concern about copyright, trademark, patent infringements. We're not sure what -- how that actually plays into it, but there was a concern that we might get into some areas that we didn't need to be into from a legal perspective. So, that's an area we need to address.

I think Marty mentioned the supporting documentation or validation. How much is enough? Maybe there's a way to identify how much information could be -- is needed to get a technology into a marketplace.

Communication of approval in the field. I guess that's not really a barrier. That's an opportunity, and I heard that mentioned already today, too. Use of this IKE System, I know it's out there. May be a good way to kind of share some information in the field as it comes up.

The next area we addressed was communication,

and I heard that addressed in the first committee group, also. But just to improve the communication of successful innovations. When something is discovered or uncovered that actually works, how do you get the information out to the rest of the industry, to the rest of the inspection agencies, so that they are aware of it, and using vehicles, such as the FSIS, industry, academic bulletins, trade journals, the websites. There's a variety of ways to communicate and trying to identify which one is the most appropriate way, and to Marty's point, everybody's got a different way they get information. So, there's a lot of ways we can share this through FSIS roundtables.

Trade associations are an excellent way to get information out, even if -- I know there's companies that aren't involved, but there's -- most of the companies are tied into something that we can get information out to them. So, communication is a big key to this.

Review regulations and approval process to make more user-friendly, timely and responsive, and again I guess that was a barrier that we identified earlier, and we thought then we need to address that and try to move that forward.

Incentives. We came up with an idea, a list

of ideas that we thought might help to get smaller companies involved, to using some technologies or even getting some technology providers to do further research, but use of mini grants, recognition awards. We were thinking, you know, if a company goes out here and just does an excellent job and they bring their Salmonella from 10 to 2, I mean, maybe they ought to be recognized and rewarded in some respect.

Financial incentives, tax relief, streamlined regulations, financial assistance for research, and I know some of that exists already, but to help some of the folks from the academia side and also from the technology provider side to do the research that's needed to identify and uncover some of these new technologies.

Validation documentation again comes back to what do we need, how much do we need, how can we identify that, so that we can move through that issue?

We mentioned the copyright, patent, trademark problems we thought we might run into, so we suggested we should probably convene a group to review those issues with regards to sharing technologies. I'm not sure. I know Collette mentioned yesterday that the Executive Committee of the AMI, for example, has agreed to share information and not make food safety a

competitive issue, and that's fine for us, but I'm not sure how that works for the technology providers. It might be an issue from their standpoint with regards to sharing information. So, we need to just address that issue and find out what barriers might exist and try to overcome those.

Then finally, using increased safety standards as a means to promote faster innovation. I think USDA mentioned it in their technology paper, that, you know, when publishing the Salmonella standards, kind of helps push forward innovation. People find a way to meet it and this was another option that was thrown out as a means of providing an incentive, if you will.

So, that's kind of what our group came up with. We actually kind of brainstormed through it, tried to come up with things we thought might help, at least provide some direction, and certainly if anybody in the group would like to add anything, please do.

MS. DONLEY: I would like just to add, I kind of stepped into this group at the last minute. I was doing two groups last night, and Point Number 6 is, I think this is an opportunity for the agency to revisit the performance standards that we have right now which the industry has just shown remarkable ability to meet,

specifically the Salmonella performance standards. I'll use the example of ground beef as a for instance.

The standard right now is that -- what is it?

Seven and a half percent, and what the achievement right now is down to 2.8 percent. So, this is a time that we start with -- that within those numbers are certainly companies that are employing new technologies, but there are also companies that are not.

So, as we ratchet the food safety standards up to tighter levels, I think performance standards, what will happen is that it will incent companies who are not employing technologies some of these available technologies to start using them.

MR. HOLMES: I like what you all worked on. Charlie, it looks good. One thing that I wanted to reiterate, and I think you've caught it really here, the one referring to disincentives on labeling. The thing that, I guess, although there are some technologies that are available that our members and some of the meat processing plants that we're aware of are interested in using and are certainly available, you get caught in the, okay, now what do I call it? I can't call it ground beef. It's ground beef with, you know, what have you, and so I think when we -- and I

know that Phil Derfler was working on this because I think we brought it up last meeting, which was, understanding that whether a technology, whether it be a spray or something, something done to the product, whether it's an additive versus a processing aid and differentiating between the two, and if it's a processing aid, hopefully having it have no disincentive to the labeling process or to the standard of identity of that product.

And so, Phil, if I remember, and I don't know if he'll be here later this morning, maybe he could address the question a little bit, as to where that stands, but it seemed to me last meeting, he had some comment to the fact of whether it was a one-time effect on a product or whether it had long-term preventive effect, so whether it was a kill product or whether it had some long-term preventive of growth of various microorganisms.

So, I don't know exactly where that is. Maybe Phil could -- we could ask him in a break and he could give us an update or do you know? No? Okay.

MS. RIGGINS: I know that Rob Post is working on the standards issue in general, and this is one of the questions that they're exploring with FDA. I know they've made some progress because they had meetings

last month, and we can get the details, but Rob Post would really -- he was here yesterday, but he would be the person to fill us in. So, we'll call back and get someone to come in and brief you. Okay.

MR. HOLMES: Great. Thank you.

And the other thing to Nancy's point, is that, you know, I think performance standards in and of themselves, as long as they're scientifically and can be supported, you know, I don't think that -- at least our organization is not opposed to performance standards as long as they're scientifically sound and applied.

MS. LEECH: Irene Leech. I'd just like to kind of remind us that when it comes to the labeling, it's important that consumers be brought along with whatever new technologies are coming, so that people don't find that something's happening that they'll understand and have questions about and then you get broadsided, and I think that's what happened with some of the GMOs and so forth, and so, I think there's a balance in terms of the labeling.

You don't want to do things that make it so people won't try things, but on the other hand, if you do things and they don't know about it and then some day, some concerns get raised, so some communication

along the way and education to be sure that consumers are up with the technology, I think, can make a big difference.

So, I think you want to be real careful about what you do and don't let people know about.

MS. SWACINA: Yes?

MR. GIOGLIO: Can I bring something up? Just, I guess, as a point of clarification and maybe I'd look to Patrick to clarify here. Do you really mean approval? We sort of have moved over the years out of the command and control and approval of equipment and technologies and maybe we're really looking at this and accepting a new technology or, I think, in your official correspondence, you probably send a no-objection letter.

I just don't want the committee to send a signal that they're looking -- I don't mean to inject myself, but just, you know, I'd like you to think about that, look at that terminology.

MR. LINK: We kinda worked through that and you're right. It's not an approval process. This is a review and acceptance and no objection-type process, yes. So, yes, maybe we misstated that.

MR. HOLMES: Let's change it.

MR. LINK: Pardon?

MR. HOLMES: Let's change it.

MR. LINK: Yes, let's do. So, we should probably call it the review or --

MR. HOLMES: Acceptance process.

MR. LINK: -- acceptance process.

MR. GIOGLIO: I don't think we want to be sending a signal where we're going back to looking at everything and putting a stamp of approval on. We've all -- you know, some of us did that for a living for awhile.

MS. LEECH: And so, there are two places that that is. It's there under Number 1, and it's also under Number 3.

MR. LINK: Number 1, communication and approval.

MS. SWACINA: Dr. Johnson?

DR. JOHNSON: Alice Johnson, NFPA.

I'd like to ask the committee or the full committee to consider under Number 3 making some sort of recommendation to the agency. We know they're working on this draft directive but maybe make a recommendation that they get this directive out as quickly as possible.

I know this Number 3 talks about timely and responsive, but since there is a specific directive

that's in the works, I think it would be nice if we identified that as something that they need to push forward with.

MS. SWACINA: What is it you want to have added?

MR. NEAL: You have some language for that?

DR. JOHNSON: No, I don't want to do any work on it.

MR. NEAL: That was his subcommittee, right?

DR. JOHNSON: That was, yes.

MR. LINK: I'm working on it. I'm working on it. So, you're suggesting we just put in some recommendation to the agency that they publish this revised directive as soon as possible. I mean, yes.

DR. JOHNSON: Give it priority.

MR. LINK: Give it priority, and I think I overheard you say maybe even provide an outline of here's how you get this done?

DR. JOHNSON: Well, yes, I think that would be pretty close to what's coming out in that directive, where they list to make it easy step-by-step, here's what you need to do when you're considering this.

MR. LINK: Right.

DR. JOHNSON: With contact individuals. If everybody agrees, I will try to --

MR. LINK: Quickly get, as soon as possible, next week. In the near future, yesterday.

MS. LEECH: Alice, would language such as this work? Request that FSIS quickly complete and distribute the revised directive with step-by-step procedure, contact information, etc.?

MR. LINK: Perfect.

MS. LEECH: Do we need to specify, give the directive a name here?

DR. JOHNSON: What would it be? 10,700.2?

MR. BURKE: So, it would be Revised 10,700.1.

DR. JOHNSON: Okay. So, okay. I can't keep up with my numbers.

MS. LEECH: That's where he needs it right now, is somewhere in there, to revise what, before he puts directive in. Okay. Whatever. Okay.

MR. LINK: There you go.

DR. JOHNSON: Right. Thank you.

MS. SWACINA: Ms. Leech, did you have something else?

MS. LEECH: No. Sorry.

MS. SWACINA: I had a question for you, if I could, on Number 4, the incentives. Is that intended to be that you're asking USDA to provide these things or what is it you're looking at?

MR. LINK: No. I don't think so, not completely. I mean, for example, the recognition awards, that could even be an industry thing. Maybe we ought to be doing something to recognize the innovators out there and kind of pump them up a little bit. So, I mean, these are just ideas we thought -- we tossed out that would help maybe but not necessarily focused on FSIS providing. But if you've got the money.

MS. LEECH: But I think we were talking about more than just money. I mean, it was you'd need a little bit to maybe make a placque or something, but, I mean, it's the recognition that's important there, even more than the dollars that go with it. Money's always nice.

MS. DONLEY: I do think that the recognition -- as far as the recognition awards goes, that's going to have to be something that's within industry because, you know, it would appear then that FSIS is promoting specific technologies, and I don't think that's what you want to do.

MS. SWACINA: Any other comments? I didn't mean to stifle conversation by saying we needed to carve out time for this other discussion.

Alice?

DR. JOHNSON: Just in looking at this, have

we included everything, any kind of communication with other agencies? We talked about FDA, but I'm thinking about some of the work ARS is doing in looking at technologies, and have we captured the communication between FSIS and other agencies in getting words out to the field? I know ARS is doing a lot of work, and I just wonder if we've captured that.

MR. LINK: It's not listed. Certainly it's okay if you want to just add in and other agencies to make sure that it's captured.

DR. JOHNSON: Would that be appropriate?  
Does the committee --

MR. LINK: From my perspective, yes.

Well, I want to thank everybody for their input on our subcommittee. Comments? We were almost as good as Subcommittee Number 1 but not quite.

MS. DONLEY: I have a question for the agency. I'm trying to remember how many years ago there was a new -- you put out a new technology public meeting, and I know it was held in Chicago. Is there any discussion about repeating that or the role of tech? It was public meetings in Chicago and it was like roles of new technology and roles of technology in food safety or something like that.

MS. SWACINA: You're saying we had one in

Chicago?

MS. DONLEY: Yeah.

MS. SWACINA: I remember one in Washington.

MS. DONLEY: Maybe it was Washington.

MS. RIGGINS: At the time that we were working on the HACCP rule, we had several public meetings, one of which was held in Chicago, to discuss the technical issues related to the rule. Issues that had been raised as a result of the proposal and issues that we thought we needed to have a public discussion and gather as much information as we could to complete the final rule.

MS. SWACINA: Do you remember when that was, Judy? Was that '96? '99?

MS. RIGGINS: '96. Had to be like '96, because the final rule came out in early '97. So, it had to be '96, right after the proposal was done.

But I can say that we do intend with each rulemaking, where there are technical and scientific issues, to have public meetings to discuss those issues. I know we've been working on, you know, the egg proposal and there are some issues there and that the likelihood is that we will have a public meeting to discuss those once we get a proposal out there and published, but I would say that with respect to most of

our rulemakings, there are going to be technical issues, scientific issues that are attendant to the rule and we will have a public process, a public discussion of those.

DR. MURANO: I'd like to add something to that. Earlier this year, we began a series of scientific symposia organized by the agency, sometimes in conjunction with CDC or FDA, and I guess my question for the committee, based on Nancy's question, is, do you see the need for us to perhaps organize one of these symposia around that specific topic by itself? Because we certainly would love to do it, you know.

There's so many topics that we want to mount symposia around. There's one coming up in Puerto Rico on pre-harvest food safety. We have one in Orlando in the Fall on food safety education. We've got all kinds of plans for other symposia but have not put one together yet on that specific topic. Is that something that the committee would suggest we should consider?

MR. HOLMES: I would say certainly. I don't know why anybody would be opposed to that. I think we're all interested in finding new ways to make our products even safer for not only ourselves and our customers but the entire consuming public. So certainly. I think that should be a priority.

DR. MURANO: I guess my question maybe, Marty, is to put you on the spot a little bit more and the other members to kind of ask you for -- just throw some ideas out as to what kinds of topics within that theme would you like to have be included, if possible?

You could just right off the top of your head right now give us some ideas.

MR. HOLMES: I think you've got, you know, some of it, you could even look at the various HACCP processes, whether it be raw ground, raw not ground, you know. What -- depending on what the products are that you're making, you could even have it divided that way, that you've got a session on each one of those possibly on just off the top of my head thinking.

Some of them could be packaging-type technologies that could have some positive effect on products. Some could be actually, you know, things that you do to the product versus the packaging. Other thoughts?

MS. DONLEY: Testing. Microbial testing.

MR. HOLMES: Sure.

MS. DONLEY: Rapid tests.

MR. HOLMES: Rapid methods.

DR. JOHNSON: What about looking at technologies that are pre-harvest? So, I know the

Puerto Rican conference, I don't think quite goes that -- into that, but it might be good to look at that area as well.

MS. SWACINA: Can I suggest maybe we add this as another bullet under Number 2, so we can capture all these ideas as well?

MS. LEECH: Sure. You could even put in parenthesis after the new technology forums and add it, like we've done some of the other examples.

DR. JOHNSON: I'm wondering if the committee -- I kind of think this is really important and this is a very good way to get this -- get word out, and I wonder if it should be like a separate recommendation, so that it really stands out and says, you know, the committee recommends the agency look into and here's some topics.

MR. HOLMES: Technology symposium.

DR. JOHNSON: Yeah. It kinda doesn't blur it in with everything else.

DR. MURANO: I have to tell you that my assistant, Andrew Moss, had kept using the word "symposiums", and I kept correcting him that it was symposia. So, he looked it up in the dictionary and it's actually now accepted, symposia or symposiums. There's a trivia thing for you.

MR. LINK: I want to include some of the discussion we just had on the HACCP programs, on the pre-harvest technologies, rapid microtesting technologies.

MS. SWACINA: I want to know how to do that.

DR. JOHNSON: This is really nice. I think all the committee will agree, instead of having it all scratched out and then new copies, this is great. Even though we're making fun of you a little bit earlier, we appreciate it.

MS. ESKIN: Hyphenated, yeah.

DR. JOHNSON: This is so much better.

MS. SWACINA: Are there other suggestions for these new technologies?

MS. KASTER: I don't think you have what Marty had said, which I thought was a pretty good idea, because then you could go through each type of HACCP plan and that would pick up slaughter technologies, ready-to-eat technologies. So, put something in there about HACCP, I don't know, HACCP plans specific or --

MR. HOLMES: HACCP categories?

MS. KASTER: Yeah. HACCP.

MS. SWACINA: I'm not sure I understand what that means.

MS. KASTER: What it means is then you would

look at technologies that were available for slaughter, technologies that are available for ready-to-eat, technologies that are available for raw product not ground, and base the structure of the technology discussion. Is that what you're after?

MR. HOLMES: Right.

MS. KASTER: Yeah.

MR. HOLMES: HACCP plan categories. I think I'd change "product to "plan", if you could, Moshe.

DR. MURANO: The other thing is that we try to have these, as I said earlier, where appropriate, have folks from other sister agencies and so forth. Are there any suggestions regarding that from the committee in terms of what -- you know, organizing these meetings takes so much effort, that you might as well, in my opinion, make it as complete as possible.

So, any ideas on what would be suitable to or would be suitable to include here that might be applicable to this area?

MS. BAYSE: Gladys Bayse.

I should think FDA certainly in terms of additives.

DR. MURANO: Additives, yeah. Okay.

DR. JOHNSON: ARS. ARS and its sister agencies.

MR. HOLMES: You're talking about under Number 2, a bullet saying presentations by other various agencies that would have potential impact.

MS. SWACINA: Yes?

MR. GOVRO: It seems like we're doing a little bit of brainstorming here, and one of the things that seems to be coming out or at least that's developed in my mind is that the agency sometimes looks at some of these problem areas in sort of a compartmentalized fashion, and I think that holding symposia like this and bringing in all kinds of different players, if you did it in the right way and had your ears out, you would become aware of a lot of ways in which these different things could interact and look at the problems more holistically.

I noticed yesterday when I mentioned the last question about looking at laboratory methods and new technology, it was no, that's another area, but I think you know, you should look at that as an integral part of the bigger picture, and I think you have an opportunity to do that with this.

MS. LEECH: Well, you may think in broad ways, I mean, things like, you know, our concern about homeland security and some of those kinds of things. There may be some sister agencies, but there may be

some agencies that traditionally haven't been really connected but that we may need to consider given changing environments.

MS. SWACINA: That's a point, too.

Okay. I was going to --

DR. PIERSON: An idea in terms of an agency that would have a tremendous amount of resources for research and technology would be CSREES, who have, for example, an integrated extension teaching and research competitive grants on food safety, and so they have a whole resource base of people who have researched these various areas and they'd be able to, you know, address the issues you're talking about. So I think they'd be a tremendous part of this. That's CSREES is what it is.

MR. HOLMES: CVM?

MS. SWACINA: Yeah.

DR. MURANO: I guess I want to ask a question, if I could, unrelated to this but related in a way. We keep talking about communication being a key for many of these areas. Both of these subcommittees brought that up as we said.

The website that FSIS has, you know, I know that we have efforts underway to improve it, and I'm very happy about that, and I guess I'd just like to

kind of poll the committee to see what -- what do you consider to be the most important avenues of communication, and if the Internet is one of those, if we can just get a very short kind of series of ideas or recommendations as to what kinds of things we are -- we should do with our website or what kinds of things we should not do. Maybe things that we're doing right now that you -- that it's so obvious and maybe we don't see it because we're -- because it's our website, you know. It's hard to critique yourself sometimes.

So, I'd like to maybe just take a couple seconds to kind of give us a little bit of input as to what -- how we can improve our website and if you see that that's really something that we have to spend a lot of time on. I think we do, but I'd like to hear your thoughts.

MR. LINK: This is Charles Link.

I guess just one thing that I have trouble with with your website since we're going to talk about it is just finding the regulations direct because I finally figured out how to get there, but it took me forever, and even then, it's not easy to get through it. So, I mean, even if there was just a take me to the regulations, take me to the directives, that would be kind of nice, and maybe -- and we've been talking

about new technologies. Maybe there's, you know, a hot link you can just take to a list of here's things that we've reviewed recently and accepted or something. I don't know.

Because part of the problem we were discussing last night is, you know, the plant that might be testing a technology knows it's okay, the folks in Washington know it's okay, but once you get beyond that, nobody knows it's okay, except those two guys, you know. So, how do you get that out, I guess, is part of what we've been trying to figure out.

MS. FOREMAN: Carol Tucker Foreman.

I use the website constantly. There's hardly a day goes by that I'm not over there thumbing through it. My husband's going to begin to sue you for alienation of affection because I'm on your website late at night.

DR. MURANO: Maybe we should not improve it any more.

MS. FOREMAN: But then I'd be really mean.

You know, frequently in the past, the agency has brought to this committee papers called current thinking. I would really like to see some of those current thinking papers go on the website. My guess is they're not developed at this point, but it would be a

terrific way to have means to have an informal mechanism for saying this is kind of where -- what we're thinking about in a particular direction on this issue right now. We're not ready to send it to the Federal Register. We're not ready to hold a meeting on it, but looking now a year, 18 months on a half dozen key issues, this is what we're thinking about now, and it might help your decisionmaking process.

MR. DERFLER: We actually are thinking about doing that or trying to think about ways of how to do that. The problem is, it takes so much effort, you know, to get something done, that you might as well send it to the Register.

MS. FOREMAN: Well, I understand. I think inherent in this is that you'd have to be willing to put the disclaimers on it that say this may change completely before it goes to the Federal Register. That's fine with me. That's -- you know, I understand that for people who like to hold all information close to the chest, that that's a threatening activity, but boy, it sure would help to get some of those issues out there, and in the case of people, consumer groups that have more limited resources, it'd give us an opportunity to consider these things in a more thoughtful fashion and to do a little research and get

back to you.

MR. DERFLER: We're actually thinking about doing that, putting stuff up on our website like that, and then announcing their availability through the constituent update.

MS. FOREMAN: Great, great.

MS. SWACINA: Mike?

MR. GOVRO: Mike Govro.

I would recommend that you do some testing for user-friendliness with people who are either not familiar with the agency or not computer folk. I think sometimes websites are developed by computer people for computer people, and if my memory serves correctly, I was on your site awhile back, and I don't go there often, and I was trying to look something up, and I became frustrated and quit because I didn't -- I wasn't familiar enough with the terminology or your organization to know where to go next, and if you don't know that, you know, looking things up on the web can be a very time-consuming process. So.

MS. FOREMAN: One other thing. FDA's website has a hot link directly to the Federal Register document in many instances, and I don't think that's true at FSIS. I've found summaries but not --

MR. DERFLER: Actually, I think we do, but

you've got to go through OPPDE or RDDS. I'm sorry. I mean, that may be the problem.

MS. FOREMAN: Mike, I think you got the answer to your question.

MS. SWACINA: I think we understand the problem.

MR. DERFLER: We can try.

MS. LEECH: Some of you all may have that problem, too.

MS. SWACINA: Alice?

DR. JOHNSON: To kind of -- it's a little off subject, but it expands a little bit on Carol, and I'm on the -- your website a lot, although not late at night. But the agency has had over the past year some very good public meetings. The applied epidemiology meeting, I thought, was great.

One of the big problems was that by the time you get word through the Federal Register or even the constituent alert, you know, people have to get cheap plane fares and rearrange schedules. I don't know whether you can do this because of constraints within your legal department or however that would work, but if somehow or another when you're planning a tentative meeting, if you had like tentative dates, mark your calendar or something like that, it would be so useful

because at least people would be aware and it wouldn't be okay, and sometimes the Federal Register announcement has come out the day after the meeting or the day of the meeting, but -- and I can understand that there are problems, but even if you could couch it as tentative, at least people would be aware and be looking and have some tentative plans made, so you could get better attendance.

MS. SWACINA: Thank you. That's a good point.

Other comments or questions? Marty, did you want to circle back since Phil is here now on your labeling questions?

MR. HOLMES: Oh, and I guess Judy kind of felt like Robert Post was probably the right person, but the question on where we were in terms of processing aid, standards of identity, labeling issues versus additives and kind of maybe where that is.

MR. DERFLER: We have a guidance document that's pretty far along that will explain it and then we also intend to do rulemaking on -- with respect to binders and antimicrobial agents in food standards. So we've got both initiatives going.

MR. HOLMES: Should we -- and I know you don't like this, but the next question is, is that

something maybe this summer? Are we that close? When you say pretty far along, I'm just kind of curious where that is in the program.

MR. DERFLER: I don't know. It would be -- it's -- I don't know. Late Summer/early Fall, I hope.

MR. HOLMES: Okay.

MR. DERFLER: Yes.

MR. HOLMES: Thank you, Phil.

MS. SWACINA: We won't say what year.

MS. DONLEY: Just one more last comment here, and I think it fits here. This would be on the new technologies symposia. I was handed this brochure. I didn't even know this -- I guess it's part of ARS. It's called the "Instrumentation and Sensing Laboratory", and they have some incredible projects going on here which, I mean, it's just fascinating that perhaps, I guess, this might be a branch of ARS and if they can participate in this, it would be awesome.

MS. SWACINA: Okay. Thanks.

Okay. Are you all ready to accept this document then with these modifications? Okay. Well, good. We're very much ahead of schedule. So, we can go ahead and take our half an hour break and be back at -- by my watch, that makes it 10:15 which puts us right on -- we're still ahead of schedule.

(Whereupon, a recess was taken.)

MS. SWACINA: Ms. Logue, did you have a comment?

MS. LOGUE: Hi. Just a quick comment, and could we revisit something that Subcommittee 2 that, you know, just kind of came to my attention? Regarding how we do some of this kind of technology research and stuff, is there any chance that we could put in some line or some discussion or some piece about getting the universities and the line graduate institutions and all these educational facilities that do a whole lot of this stuff already, getting them kind of lined up or some kind of partnership, you know, with industry and with all these other -- and with the FSIS to look at, you know, how we could get this together or how we could work some of this technology in and, you know, kind of promote this kind of an alliance? Could we go forward with this or put this in as a possibility?

MR. LINK: I just -- I have a question, Catherine. All the research the universities are doing, is there kind of a clearinghouse so you can see what they're actually working on?

MS. LOGUE: It depends on where it's been kind of funded through. Some of it, if it's USDA kind of CSREES, they have what they call the "CRIS" System,

C-R-I-S, and that gives you kind of like a short summary of what's going on and then each year, people, you know, somebody like me would have to put in a new paragraph each year saying, well, okay, this is what we've done in the last year of our research. So, there is that kind of a system there, and I did talk to some guy from DoD recently who was actually looking to add people to this kind of a clearinghouse thing, and they were looking at it for further beyond just food safety research or technology, but they're looking at other things as well, DoD stuff.

But, yes, I mean, there is a clearinghouse available right now, but what I'm thinking of is here, you know, to put this in as a recommendation that we look at uniting FSIS and industry and academia working on this technology, which I might add a lot of universities are already doing anyway.

DR. JOHNSON: This web link, is it on part of the FSIS page? Is it easy to get there? Is it --

MS. LOGUE: I don't know. I don't know if it is. I know it's through the NRI section is where I get to it.

DR. JOHNSON: Do they keep it updated?

MS. LOGUE: I think it gets updated every year, yes.

DR. PIERSON: Where you'd find it is if you went to the USDA web page and talked about agencies and then you'd go into CSREES from there, you'd -- that's the way to go through it.

DR. MURANO: We should link it.

DR. PIERSON: We could link it through FSIS.

MS. LOGUE: That would be good.

MR. HOLMES: Did I understand, you go to USDA CREES and then to CRIS?

MS. LOGUE: It's known as the CRIS Forum. That's what we call them, and I think the link is called CRIS but I can't swear to that. I don't remember.

DR. PIERSON: Also in the CREES page, you'll find food safety, and in food safety, it'll list all the project areas that are in the progress reports that have been funded.

DR. MURANO: We should just link to that.

DR. PIERSON: Yes, we can just link to that.

MS. LEECH: But that doesn't necessarily get at all the research that's going on even at the land grant universities because, you know, for example, the work that I've done, my whole career at my land grant university, they've told me I -- no use even bothering to submit a proposal because the kinds of things, you

know, that they've got locked up for long periods of time and so forth. So, you know, there's probably some work going on even in those universities that might be of interest, you know.

Particularly we might want to think about as we're thinking about new technologies, some of the projects that might interact with consumer versus -- as well as some of the traditional areas and so if we could do anything to encourage those folks to broaden their perspective on what kind of projects they'd look at, that would be helpful as well.

MS. LOGUE: Well, then, does it come back to this idea that we need a kind of a difference-type of clearinghouse, something that covers not just what the USDA funds but, you know, there are things that are funded at like state level and local level and university level that you wouldn't get into the CRIS System?

I mean, I've had some of my research funded through different agencies, little small things that wouldn't be accounted for. So, I don't know. Do we need to recommend that there's some kind of a clearinghouse or something that people can, you know, add information to? You know, here's what we're doing right now, if somebody's interested.

MS. SWACINA: You have some language you want to add that people can react to?

MS. LOGUE: I don't know. Let me see. Recommends the creation of some kind of a clearinghouse or help towards the development of a clearinghouse for food safety research and technology research which could be applicable or is applicable to industry and to the FSIS. I don't know. Help me out here. Anybody got any ideas?

MR. LINK: I can't help you on the language. I think it's a good idea. The CRIS -- you call it CRIS? I'm not sure what you said.

MS. LOGUE: CRIS.

MR. LINK: That's available to FSIS now?

MS. SWACINA: No. We don't think the link is there. It's on the USDA website. You can get a link from there, but we'll have to work on the FSIS link.

MR. LINK: Right. And Irene's point is there's a lot of research going on that's probably not listed in that particular spot that we ought to be able to access, and I support putting the recommendation in there to find a way to do this. I'm just not sure what language we ought to use.

MS. SWACINA: You want to make that a new Number 3?

MS. LOGUE: 3 would be a good idea.

MR. HOLMES: Does the American Meat Science Association and maybe ERMC and that kind of thing, are those things -- would that be included in all of this or is that separate research that wouldn't be found in --

MS. LOGUE: Right now, I don't think that would be found under the CRIS. If that's funded through the American Meat Association, that wouldn't be there, unless the American Meat Association has its own, you know, data bank or some kind of --

MR. HOLMES: That might be another trade association that really, you know, you think about it, we don't -- they're not typically here. They're not, you know, but the American Meat Science Association and some of the things that are going on there, that may be a missing tool that we really haven't -- you know, maybe at some point next time, it's time to add people to the committee. There may be somebody from MSA or something that could be looked at to add some input on this committee. I don't know. Just a thought there.

DR. JOHNSON: We maybe want to be sure that when the agency looks at these workshops, that they include the Meat Science Association folks as part of -- they poll them to see what work is going on and

include them as part of our public meeting on technology.

MR. HOLMES: I've just been informed we have one of their board members sitting on the committee. So, I retract my statement.

MS. KASTER: I probably should have mentioned that yesterday. I don't realize we were elaborating on that, but I do sit on their board of directors. I have another term yet after this year. So, what I'd be happy to do is, you know, carry that to our next board meeting and then perhaps we can facilitate some kind of interaction on that. I know that they'd be really exciting to work toward that. It's the kind of service-type thing that we're looking to do.

MS. SWACINA: Is that language accepted by the committee?

MS. LOGUE: Together then?

MS. SWACINA: Sorry?

MS. LEECH: That's -- I'll just throw this out and then that may cover it, because, see, I was sitting here writing, too. Seek ways to link research conducted at universities, especially land grant, and including that supported by both experiment stations and other funding, encourage innovative interdisciplinary research.

DR. PIERSON: Let me suggest that, you know, again within CSREES, you have your national program leader for food science, and, you know, even though there are projects that don't exist on the CRIS System, they have, you know, the national program leader for food science would have the database relative to the universities and all the contacts and an avenue maybe to work with that, with the national program leader and to see how such a database could potentially be formulated.

I know that that particular position, for example, put together such databases for, oh, the research centers for food processing and activities associated with them. So, you know, there's these mechanisms through which it could be worked.

DR. JOHNSON: While he's finishing that up, I just have one comment about somebody made the comment, what's the most important communication, and I think we've got to be sure we're talking all these great tools and we want to be sure, I think, that we need to go to the basic level of dealing with the IIC and be sure that the IIC is up to speed, as Nancy mentioned some of the horrors that she had heard about in plants that are using technologies, but the IICs particularly in the smaller plants, the best way to get acceptance

for some of this technology and exploring the technology is with the knowledge of the IICs because a lot of the times, the plant will go to the IIC and talk about it first and that's, you know, if the IICs up on some things or even provide them with a list of links that they can give to the companies to say, hey, here's some ideas and here's what's going on as far as innovation.

MS. SWACINA: Does that need to be added as language as well?

DR. JOHNSON: I just wanted to throw it out as a reminder that we --

MS. SWACINA: Okay.

DR. JOHNSON: -- do need to keep -- we've been talking a lot about how we keep industry and the awareness up, but I think it's real important that FSIS folks at the field level are aware of what's going on, too.

MS. SWACINA: Okay.

MR. LINK: Also, while he's doing that, I don't want to get ahead while he's typing, but Alice made a comment about, I guess, Number 2 with the workshops, to make sure we include the people doing the research at universities, and I'm not sure if we need to even say that. Maybe it's assumed that your

universities, industries, technology providers will all be or should probably all participate in these workshops, but it's probably assumed. Maybe we ought to just say it.

MS. SWACINA: Dr. Denton?

DR. DENTON: In thinking about how you do this most efficiently, looking at other funding agencies, there may be the potential to link with other agencies that do funding -- not agencies. I'm sorry. External funding, industry-based, such as the NCBA, the American Meat Institute Foundation, and the U.S. Poultry and Egg. I'm sure that each of these funding agencies has their own reporting system within their website that may be an easy way to get at some of this funding that doesn't appear in the CRIS System and the CSREES System.

MS. SWACINA: Thank you.

Okay. Is this acceptable? Are there additional comments? We can close out Subcommittee Number 2?

MS. LEECH: Moshe, do you want a space between that?

MS. SWACINA: Okay. Let's move on to Subcommittee Number 3.

Collette? Ms. Kaster?

## Standing Subcommittee Number 3

MS. KASTER: All right. First of all, I'd like to thank those subcommittee participants. I thought our session went pretty smoothly. We had some good discussion. I'd like to especially thank Bryce Quick and Dr. Leese for their insight and Dr. Leese's experience with the states and also Dan Englejohn. He did a fantastic job of taking notes on the flip chart and posting them up almost faster than we could read them or capture them into ideas. So, he really went to town for us.

We had three questions that we were to address and again the topic is related to Farm Bill provisions on interstate shipment of state-inspected products.

The first question is basically about resources. So, it's because the review provision is not subject to appropriations, how can FSIS best use its limited food safety resources to meet the mandate?

We came up -- we had a lot of discussion around this area, and every time it comes up, there's a lot of historical discussion about funding and how things have come together, but what we wanted to do was come up with something tangible because it was felt that the reviews needed to be completed by March of 2003.

So, what we did was we started talking about the reviews that are done on an annual basis. There are six to eight of those done each year. We felt that we could go back to 1999 and incorporate the reviews that had been done back to that year. The reason we selected that year was because that would incorporate back to the small plants implementing HACCP and then because we didn't want to really assess reviews that were done prior to the inclusion of HACCP.

We had started with the year 2000. That kept the number down pretty substantially and left a lot of years of review to be done yet, and so what we had said was that in the year 1999, look and see if the states that were included had a proportional number of plants that would be in the small category versus the very small.

Dr. Leese indicated that that would get us to a number of about 21 state comprehensive reviews, meaning that there would be six or seven left to do. Six, I believe, left to do, and so the attempt would be made to complete the reviews of the remaining states by March of 2003, and what we really said is that that probably needed to be done by December of this year in order to write the report and present that back to Congress.

So, the second part of our discussion there was that if the time frame was too restrictive to complete that, then consider requesting additional funding and use that funding to either bolster the existing resources or to consider outsourcing the reviews through some kind of source or an additional option would be to pursue an extension for the due date of those reviews.

I'll work through each of the questions, unless somebody has discussion, and then we can come back and hit specific topics. Any of the subcommittee members, if I've missed anything, please chime in.

MS. FOREMAN: Collette, may I ask a question, please? I think I don't understand something.

The -- if you go back to 1999, that's the very -- that's the small plants. 2000 is when the very small plants came in. The very small plants are the ones where you're likely to have the largest number being state- inspected.

Why would we not want to make sure that you include only reviews that covered those -- that took place after the very small plants came in under HACCP?

MS. KASTER: That is where we started for the reasons that you said, but it was a much smaller number, as you can imagine. It ended up being 12 to

15, and we didn't really word it as specifically here, but what we had kind of said is take a look at the year 1999 and look at the states, and if there are states that have a higher representation of smalls rather than very smalls, then try to go ahead and use those reviews as well, but if one of those states showed up and it only had very smalls, then it probably wouldn't make sense to include that as one of the review criteria. So, that 1999 year would be one that would be viewed a little bit more cautiously as to whether or not to accept those reviews.

Basically, what we were trying to do was whittle that number down so that the remaining ones, there weren't as many.

MS. FOREMAN: I understand, and I'll just hold off now. I may want to have some discussion on that, but I'll hold till you go through because now I understand.

MS. KASTER: Okay. Thank you.

The second one, what kind of guidance would be useful to states in advance of legislation authorizing interstate shipment?

We talked a little bit about this yesterday, and I think everybody felt that as a cornerstone, we would request that the states adopt all current federal

food safety regulations and their implementing policies, including notices, directives, and memoranda.

Mike Mamminga indicated that that was typically the case, but I think we wanted that to be said for the record as well.

Secondly, ensure uniform compliance between the state and federal regulatory requirements, and then, finally, use deficiencies or gaps, as Dr. Leese called them, identified in the state comprehensive reviews to formulate any additional guidance material. As part of those reviews, there is an analysis of these discrepancies or gaps, and then some follow-up procedures are done and so we would go back and take a look at that information and use that to help formulate material as well.

Comments on 2? For now, I'll go to 3 then. Okay. Finally, the last part was a pretty open-ended question. The final part of the question says: in light of recent events, does the committee have any additional concerns with the concept of interstate shipment of state-inspected product or with its implementation?

The committee felt that the recommendations under Questions 1 and 2 should be initiated now. However, simultaneously, there should be consideration

given to the following things. What we did was we came up with a list of potential concerns or things to be considered during implementation.

Most of us read the wording that said in light of recent events as meaning post-September 11th and that is why food security made its way on to the list, and basically what we're saying here is that give the same thought process to food security in this scenario as we would to any federally-regulated plant.

The second point was, performance standards are under scientific review and so would be very cognizant of that as this is being -- as these additional plants are being incorporated. In other words, ensure that whatever comes out of these types of reviews is applied to these plants as well as to the current federally-inspected plants.

Another concern was the sustainability of state inspection programs and inspection resources. Again, as Mike Mammaing pointed out, these are somewhat tenuous with the current economic situation in many of the states and so probably be cognizant of that before expending a lot of resources to assimilate them with the federal program.

Finally, I think this fits pretty well with our theme of particularly Subcommittee Number 1 but

also some discussion about communications with Subcommittee 2, and that is, ensure that the state-level people in those plants have the same training and exposure to federal inspection meetings, for example, the correlation meetings, and just make sure that that line of communication is open.

So, with that, I'd first ask the subcommittee if I've missed any critical points on this and then open it to the rest of the committee for questions or comments.

DR. JOHNSON: Collette, I know that some of the folks that weren't on this subcommittee but were in the back of the room had some concerns with some of the issues that we had put up. Do you want to talk about any of those?

MS. KASTER: With the list of concerns?

DR. JOHNSON: Well, with some of the issues that we had talked about in this -- in our subcommittee group.

MS. SWACINA: Would you like to go ahead and elaborate on those?

MR. NEAL: You're on.

DR. JOHNSON: I told them to talk to you because you were going to lead the discussion.

Well, I know that -- and Bernie, I'll just

call the name because Bernie had some concerns about security.

MS. KASTER: Yeah. And I think that's why when I discussed food security, I mean, I don't think that we're saying that small plants are at a risk or state-inspected programs have a different risk than federally-inspected, and I think what we're saying by mentioning food security is that ensure that that line of thought is there with these programs, the same, no more, not necessarily any less than with the federal programs.

So, it's definitely not to say that we believe them to be the greater security risk. I think Bernie's point and Marty's made the same point, is that, in fact, sometimes these smaller facilities could be considered more secure. There's much fewer employees. Everybody knows everybody as opposed to our larger facilities where we don't know every single person, and in theory, it could be easy for somebody to infiltrate.

Alice, does that cover that?

DR. JOHNSON: Yes.

MS. FOREMAN: Let me respond first to that, and then I have a series of things I'd like to ask.

I want it known that I just disagree with

that conclusion. I believe the small plants which by their nature do not have security provisions, you can't get within a mile of an IBP plant. You can walk in to some of these other plants very easily. I know they don't distribute to very wide numbers of people, but they are more open and there is, I believe, objectively a greater chance that somebody could get in there. So, I disagree, if that's what the subcommittee intended. It's at least not unanimous.

MS. KASTER: Can I make one counterpoint to that?

MS. FOREMAN: Yes.

MS. KASTER: Which is, totally agree with you about IBP, but there's an awful lot of plants between an IBP and between the type of state-inspected plant that I think that you're envisioning, and there's every different gamut of security levels at all those plants, depending on priority within a company, resources and that sort of thing. So, I think the main point is just to say that, yeah, there might be security issues, but there might well be ones with ones that are currently under the federal program and that just by the nature of being state inspected, it doesn't indicate that the security isn't there.

MS. FOREMAN: The question is, if FSIS, the

USDA, has set up, as we're going to hear this afternoon, some security procedures, does Ohio have security procedures?

DR. JOHNSON: Dr. Leese, in your comprehensive review of the state programs, with the September 11th events, have you guys talked about incorporating -- I know that you're putting out all this good information to the smaller plants, but as part of that comprehensive review, are you guys looking at doing anything on security?

DR. LEESE: We haven't up till now. Of course, the information coming out from FSIS has been rather recent, and it's shared with the states, of course, and I know the states have several initiatives on their own that they're working with independently as well as what they're working with other aspects of USDA, other parts of their state, but I'm not familiar with the details on those, but the point is well taken.

MS. FOREMAN: I think that it is important for FSIS, USDA, to try to get the states to follow along and take some of the steps that FSIS is urging the federally-inspected plants to take.

I'd like to make a couple of brief points and then come to one that I suspect will start some discussion. First, --

MS. LEECH: Carol, can I add one item on this previous discussion?

MS. FOREMAN: Sure.

MS. LEECH: I know that Virginia, for example, is at least working on that. Our Commissioner of Agriculture is very concerned and our Food Safety Committee has talked about some of those things. So, I know, you know, at least in some -- maybe our proximity to D.C. is a part of the issue, but in any case, I can give you at least --

MS. FOREMAN: It is where the Pentagon's located.

MS. LEECH: I can give you at least an example of one state that I know is working toward it because we've talked about it.

MS. FOREMAN: Let me run -- first, on Question 1, I'm really concerned. I understand the balance you had to make between the large number of states that you might have to go back and rereview and not doing the very small plants, but it would seem to me that it would be more useful to make it 2000 and then ask for additional funding or a slight -- my feeling is that the Congress would probably be inclined to grant an extension and by and large, federal agencies almost never meet their deadlines anyhow.

I happen to think it would be better to formally ask for an extension than to just not meet the deadline, but I think if the Congress realized, the ag committees realized that you don't have the money and you do have a long time, that an informal conversation might result in an extension of the time frame there.

MS. SWACINA: I think we have a form letter actually asking for an extension.

MS. FOREMAN: Well, fill in the blanks.

MS. SWACINA: Exactly.

MS. KASTER: Can we just address each one as you bring it up?

MS. FOREMAN: Sure.

MS. KASTER: Because to me, that one is one that, you know, maybe was kind of driven by the FSIS folks that were there, and the logic is pretty sound for what you're saying. I mean, certainly the committee discussed that and we decided, you know, to kind of extend it out as we could, but if you think that it's rational to go and request the extension, then I think that could support that logic.

DR. JOHNSON: Yeah. We actually talked in the committee about, okay, if you can give like a preliminary with, is there a real need to do the 27 states, can you give a preliminary and say, you know,

with additional funding, we can complete the project or go through some sort of exercise like that to at least show intent that you've looked at as many plants as you can justify would fall in the very small category.

MS. KASTER: Go ahead then.

MS. FOREMAN: On Question Number 2, we've been talking about the field force, and I wonder if you could request the states to have all of their inspection personnel participate in federal field force training operations as part of the way to get ready if everybody's going to have to be truly equal to them having sufficient training might make a big difference there.

I understand there's some funding issues, but if the Congress ever passes this legislation, they might be inclined to make a small amount of money available to assure that kind of training.

Dr. Leese, do you see any problem with that?

DR. LEESE: I didn't catch the first part that you were saying as to, are you referring to the security training?

MS. FOREMAN: No, no. Sorry. On Question 2, what kind of guidance would be useful to states in advance of legislation. I think that one thing is -- and we've got request states to adopt all current food

safety regulations, etc., and I think it would be useful to add a training bullet there and in fact if the Congress gets around to passing this legislation, we might want to suggest that they include a specific provision and a little bit of money for training state inspection personnel, so that they have the same kind of training the federal people do.

DR. LEESE: If I could comment on that? The very last bullet on the page sort of touches on that as well, and certainly, I support the concept that it's a difficult situation as far as all the new things that are coming up within FSIS, but at the same time, it's extremely important that the states have the opportunity to tap into any of the new training that's being developed within FSIS. So, we certainly would support that.

MS. FOREMAN: Just for the committee, the people in Congress who want this legislation to pass are so enthusiastic about it, that I think that asking for a small amount of money to enable good training would probably be something that would be easily, fairly easily accomplished within the Congress.

I don't think that it requires us to go a whole lot further about it, but I'd suggest that FSIS consider that and if and when the legislation starts to

go through, because if you make training available in these states that right now are so strapped for funds, nobody's going to be able to come up with training money for -- Mike, you got any extra money to train your inspectors?

MR. MAMMINGA: Yes, we do, Carol.

MS. FOREMAN: You do?

MR. MAMMINGA: Painfully obtained. I have some comments on this one when it's my turn.

MS. FOREMAN: Okay.

MS. KASTER: You say you do have some comments?

MR. MAMMINGA: Yes.

MS. KASTER: Okay. Because we've got John and Marty, and are your comments on the topic of training?

MR. MAMMINGA: Not necessarily, no.

MS. KASTER: Want to circle back around then? Okay. Go ahead, Mike, if you want to talk about training.

MR. MAMMINGA: Yes. Dr. Leese, you can correct me if I'm wrong, but right now, states really have only two options in training. We either send our staff to the FSIS Training Center which we have done for 30 years or they have to have trainers that are

certified by the FSIS Training Center, isn't that correct?

DR. LEESE: Yes, that's correct.

MR. MAMMINGA: So, they either get it at the training center or they -- if they have a big enough staff with a big enough turnover to have that kind of support on the state program staff, then they send their trainer or trainers to the FSIS Training Center to become a certified, approved, appropriately-trained trainer to go and take that message home.

So, I don't think we have a lot of variation in training out there amongst the state programs, other than do you travel to the training center and get it or do you keep FSIS-trained trainers on your own staff?

DR. LEESE: Can I comment? I think one of the factors that comes into play here is that FSIS is in the process of innovating new training procedures because they're modifying the FSIS program, and the states would not have advanced awareness of this until it's developed, and at that point, their budgets would already be developed for that particular year. So that, it would be -- it's -- even if the resources were available to present the training to the states, which is an issue in itself, there's also the fact that would they have the resources to send people to training, for

example? So, the whole issue of funds for training is very near and dear to me as far as the state programs.

MS. FOREMAN: I'd like to give you a little help on that.

MS. KASTER: What I would propose -- Alice?

DR. JOHNSON: Just kind of curiosity. Mike, can I ask how much you project that it costs to train one?

MR. MAMMINGA: Well, if we utilize the FSIS state courses that are offered usually twice a year, some time in September and again in March, February or March, and we can back-to-back slaughter and process training, and then now add on another week for FAME training, because our people are all equipped with FAME computers, you're probably talking between \$2,50 and \$3,000 a person which is subject to the 50/50 cost-share.

MS. KASTER: Any other discussion on training?

(No response)

MS. KASTER: What I would propose is that under this fourth bullet point, that we change that to -- we remove the training part from there and we say exposure to federal inspection meetings, and then back up above, under Question 2, under Guidance, that we put

inspection personnel participate in field force training and make that part of the guidance.

Anybody have any issues with that?

(No response)

MS. KASTER: No? Okay.

MS. DONLEY: Can I ask a very basic one-on-one question? What level -- who gets the training? What level of inspector? How far down does it go?

MR. MAMMINGA: You asking me, Nancy?

MS. DONLEY: I'm asking anybody.

MS. KASTER: Mike, you can speak for Ireland and maybe Dr. Leese can comment more from a national perspective.

MR. MAMMINGA: Well, we do not have numerous levels. We have meat and poultry inspectors. We have compliance officers, and we have supervisory veterinarians. They're all trained in basic meat and poultry inspection. They're all trained in process food inspection. The veterinarians are trained as a part of the state training offered in their veterinary dispositions, and then from time to time, the USDA Compliance staff offers training for compliance officers through some sort of an agreement they have with the Bureau of Alcohol, Tobacco and Firearms, and so we send our people to that.

We train every person with inspection responsibilities, at least in the history of our program, have come through the ranks, so they're already trained meat and poultry inspectors with field experience before they become compliance officers. That's what we do.

MR. SMITH: Let me -- yeah. Our GS-5s and GS-7s are responsible for any more post-mortem inspection and receive training in that. Our veterinarians, as Mike was saying, receive training in their responsibilities. Our processing people, there's usually two layers. There's when they do their offline responsibilities, which is usually SSOP, allied slaughter activity, and raw processing, and then we have other courses that get more involved with the HACCP processes associated with RTE products and shelf stability.

We now have our consumer safety officer training that is focused at training on scientific assessment of the HACCP programs, SSOPs and the interaction of those programs. We have frontline supervisor training. So, at each step of the way in their responsibilities, there's a training associated with that.

We also have inspector education programs,

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and we also have supervisory personnel education programs of which they receive college credits for.

MS. KASTER: Other issues on training?

MR. HOLMES: Instead of just doing this with a scatter gun approach, I'll just hit -- a thought on Question 1 that has just kind of come to mind. When we'll get to 2 and 3, I'll have maybe something else.

But on Question 1, I was curious. Bill, when you go to state programs and their reviews, you're obviously get information of how many TA plants there are. I mean, is that part of the process? I assume some of the information you gather.

DR. LEESE: Well, we have the information on how many TA plants there are, but they primarily link into the district system in that the state coordinator of the TA program is very comparable to a circuit supervisor within that district and could be interacting at meetings that would be set up for circuit supervisors and would be working hand-in-hand with the district manager somewhat similar to if he were just a conventional circuit supervisor, and then his inspectors, of course, which he would be supervising, would be state inspectors working in the state plant -- federal plant.

MR. HOLMES: And thank you, and I thought

that's kind of what the way it worked.

My question is, is there any interest from the agency or has there ever been any thought from the agency to encourage plants moving to a TA program or is it just, hey, it's here, if you want to use it?

DR. LEESE: Did you want to address that before I comment or not?

MR. SMITH: The TA, what it's evolved to today, is more of a best utilization of resource strategy. So, it's who's got the folks in the area that can do the coverage. So, it's not a matter of one system being better or different than the other. It's what is most efficient use of resources.

MR. HOLMES: I guess that's my -- that's why I'm -- we're talking about resources and that's why it comes to mind with Question 1, because we are talking about the agency's resources, and so you're saying based on the resources in the area, whether or not it should be a federal versus a state TA.

MR. SMITH: It's the federal plant.

MR. HOLMES: Right.

MR. SMITH: No doubt about that. What the issue is, is if we don't have a -- let's say a body in the area but the state does --

MR. HOLMES: Okay.

MR. SMITH: -- who's not fully utilized, then it makes sense to cover that through a TA agreement. On the other hand, if the state doesn't have somebody in the area and we do or there's nobody in the area, then we have a choice as managers of whether we want to commit a staff of federal or ask the state to do it.

MR. HOLMES: Okay.

MR. SMITH: Those are all resource decisions.

MR. HOLMES: That helps me. Thank you.

DR. LEESE: If I could add to that, in the example of a state plant that decides that they need to go interstate and therefore they go federal, then the decision would be made, does it make more sense to maintain that within the Talmadge-Akin system that's already in place within the state or are there federal resources available due to the constant changing dynamics of the district that it would make more sense for the state to totally drop their involvement with that plant and have it go to a federal, but either way, it's a matter of resource utilization rather than a choice for a packer.

MS. KASTER: John?

MR. NEAL: Yeah. Are you all done with this part of the --

MS. KASTER: You can touch on whatever you

want.

MR. NEAL: My question was back on food security which is in here, and, you know, I understand our concerns about biosecurity and security everywhere, but, you know, you know, we're talking about small plants and very small plants, and one thing that's going to do, if you don't bring state plants in, it's going to -- if you decide you're going to put security measures which, Number 1, I don't think you can really do other than lock your doors, in small plants, very small plants.

We're talking about 10 employees, maybe 20, but I think maybe sometimes we perceive that because we're always talking -- most times, we're talking about industry, that we're talking about large numbers and large facilities and people that sometimes you don't know, especially if you're management. You don't -- I never saw that guy before in my life.

In a small plant, my concerns are what are we talking about here for security? I mean, are we talking motion sensors, concertina wire? I mean, you know, I mean, you're -- you know, you lock the doors. You know who goes in and out of your store, and you start penalizing and saying that you have to have a said amount of -- that there's a risk factor involved.

It's a risk assessment, you know.

I mean, there's not -- you know, it's not going to happen in St. Joe, Arkansas. I mean, we can only put so many hands out the door to so many tourists. I mean, that's not where people are -- that's not what they're out for, you know. Security is security, but we have to have a reason for it right there. You know, what kind of measures do we want? Is it pertinent to the fact that we're -- if you interstate ship, which during this time of year, you might ship 20 packages once a week, or is it the fact that -- is it any small business, whether they ship interstate or not? Food's food in that sense.

I just, you know, wanted to know, you know, Carol had some concerns about small business and they need to come up to this, but I don't see where you can put any incentive besides lock the doors because you know, nobody goes in and out of your secure areas and they can come in your retail area, but they don't go in and out of your secure areas without you knowing it and your employees won't let them back there either. So, that's my question.

MS. KASTER: Maybe I'm going to oversimplify this.

MR. HOLMES: That's fine.

MS. KASTER: But we're not talking about including -- measures to me sound pretty regimented. I thought what we were talking about and what I was wondering about doing was including up where we say request states adopt all federal food safety regulations, blah-blah-blah, directives and memoranda, that they would review the guidelines because security isn't going to be mandated, I don't think, to anybody, is it? I mean, we can't say you have to have a recording video camera, you know, monitors, concertina wire, but that doesn't mean that everybody shouldn't take a look at security guidelines and consider incorporating what's again practical to their business and the risk to which they're associated.

Would that capture what --

MR. HOLMES: Yes.

MS. KASTER: -- everybody's been talking about it?

MR. HOLMES: That would capture it, but I think some people have the idea that there are going to be security measures and mechanical or physical security measures taken at big facilities or little facilities, and I'm just trying to clarify that really to make sure that that wasn't the case because I don't believe you can make people do that, you know.

MS. KASTER: I would agree with that.

MR. HOLMES: Yeah. I understood what you said and you said it the first time, but I agree. Okay.

MS. KASTER: Okay. Okay. We had -- we were going back to Carol. Then we've got Marty and Nancy. So, Carol, do you want to --

MS. FOREMAN: Yeah. Please. Thank you.

MS. KASTER: -- start back in?

MS. FOREMAN: Looking at the Question Number 3, in light of recent events, does the committee have any additional concerns with the concept of interstate shipment? Some people read that as food security. I read it as coming out of the department's abandonment of the using Salmonella performance standards in the way that they were originally intended.

I want to go back on some history here. The consumer members of this committee supported the concept paper and supported the legislation. I went to Congress and testified in favor of the legislation of shipping interstate state-inspected meat in interstate commerce with the provision that there has to be an objective measure of whether food coming off the end of the line in a state-inspected plant is as clean, as safe, as least likely to cause foodborne illness as

that coming off the end of the line in federally-inspected plants.

At every stage of the discussion of this issue throughout years in this committee, that was the one thing that each of us said was basic to our support of it. Both the GAO and the OIG have written reports indicating that state inspection is frequently not the same as, that the enforcement applied is not the same as. There are some states that have programs that are first class and there are some states that have programs that are not. Short budgets exacerbate the problems in those states that are subpar but still have state inspection programs.

I would like this to have added to this that some members of the committee will oppose interstate shipment of state-inspected meat unless and until there are objective measures to determine whether the product coming off the end of the line in these plants is truly equal to that coming off the end of the line in federally-inspected plants.

I can't allow anything to come out of this committee that doesn't make that point. It doesn't have to say it's majority but it has to say some of us feel that way.

MS. KASTER: Well, and the committee papers

in the past have reflected multiple opinions, but what I am wondering is, if inherent to some of the things that we've already said, which is, having these plants be in line with federal regulations, implementing policies, notices, directives, and memoranda, if that doesn't --

MS. FOREMAN: It's what the law says now.

MS. KASTER: -- incorporate that.

MS. FOREMAN: That's what the law says now.

MS. KASTER: So, how do you want to --

MS. FOREMAN: It says they have to be equal to.

MS. KASTER: But how do you want to word what you're saying?

MS. FOREMAN: That some -- that there has to be an objective measure. There is now no objective measure of whether raw meat and poultry -- certainly with processed product, there is. Anybody can go read the temperature gauge.

But for raw meat and poultry, there has to be some objective measure that the products are as clean and as safe as that coming out of federally-inspected plants, that they are meeting a public health-based performance standard.

MS. KASTER: Okay. I think we've got Alice

next on a comment to that.

DR. JOHNSON: We talked -- Nancy brought this up in the committee, the subcommittee, Carol, and we talked -- we felt like that we had it covered when we dealt with current federal food safety regulations and policies, notices, directives, and memorandum. We also, when we were talking about the concerns, we indicated under performance standards and any type of determination that the agency makes based on the scientific reviews that are going on right now, that those would just inherently be included as part of the state requirements as whatever comes out of these studies is included into federal regulation. So, we did talk about that and we felt like that we wanted to put it down under concerns to be sure that it was captured, but we did say, you know, it's kind of inherent, and if they're enforcing federal regulations in the state plant, then after whatever recommendations are taken under consideration from these studies, they would be included in that.

MS. FOREMAN: But, Alice, I stuck my neck way out over state-inspected meat. It had been opposed by your organization, by the American Meat Institute, by the Food Marketing Institute, for years, and we sat in here and we worked something out that said consumer

groups would support it after the industry had opposed it for years.

I went up to the Hill and testified in favor of it, based on the fact that there would be pathogen performance standards in place. That's been cut out, but the fact that some of us, the people serving on this committee, and our organizations went up to the Congress and were supportive of this legislation gave it new life in the Congress, and now I'm not going to be part of anything that suggests that I think this should go forward without that. It has to -- I'm sorry. We may just have to say that the committee's divided on it.

MS. KASTER: But I don't -- I guess I'm still genuinely asking the question. I don't understand how that is not included in here.

MS. FOREMAN: Because it doesn't say that. Unless you say does the committee have any additional concerns, I have an additional concern since the last time we dealt with this, Supreme Beef was handed down, and the Department of Agriculture is not enforcing pathogen performance standards even in those plants that weren't covered by Supreme Beef, and in the absence of that, I gotta say I'm absolutely opposed to the interstate shipment of state-inspected meat until

there is something in place that assures that product coming off the end of the line meets a performance standard for limiting pathogens. I just -- I can't go anywhere else on this.

MS. KASTER: Well, the only reason that I was asking the question is because to me, and we talked a little bit about this last night and I'll turn it over to Alice and Nancy, is that, I think your concern is a federally-based concern, and so I just felt like when we were not including states in the wording that we talked about federal regulations, that we're almost penalizing the state people for a concern that you had on a federal basis.

MS. FOREMAN: No. I want the state -- I want the products coming off the end of the line in state-inspected programs to show, to be able to show objectively that they're meeting some basic performance standards for limiting pathogens. It has to be there.

They have not in the past in all cases been equal to federal. That's a myth. I ran these programs. Everybody knows it's a myth.

Now, in some states, they're just fine, but I can tell you that in others, they're not, and I have a number of concerns. The question asked, do I have concerns, you bet, I have concerns.

MS. KASTER: Alice, then Nancy.

DR. JOHNSON: Carol, not having been on the committee in 1997, they did bring the draft of the recommendation that I'm assuming was part of the recommendations from the committee, and it did talk about the Secretary will be responsible for performing the sampling and testing for Salmonella state-inspected meat and poultry products to determine compliance with pathogen reduction performance standards. The Secretary shall conduct other tests, dah-dah-dah.

So, I think the agreement on the committee was that the Secretary will enforce standards, federal standards as was currently imposed under the HACCP pathogen reduction rule. I understand your concern, and I respect that you feel like you -- it needs to be a part of some of the concerns that have been raised. I don't have a problem with putting that on there as a concern to be sure that it's recognized.

I do have a problem with holding interstate shipment in the state plants hostage over this issue. I think that we've got several things in place, and we're going to get a resolution to this issue, hopefully within the next few months, based on these scientific reviews, and that there will be some objective measure that you can actually use to look at

public health objectives in reducing and looking at the role of microbiological testing.

Now, I think the agency is going to do something with the recommendations from the scientific reviews, and I think it'll meet what you're looking for, objective, a measurable objective, to assure that the product coming out of a plant is appropriate, but it'll apply for state as well as federal plants, and I think the review process that's in place now will give you the standard that you need, but it'll have some scientific basis to it.

MS. FOREMAN: I'm less sanguine about that than you are, but the fact is that the consumer members of this panel, certainly Nancy and I, went forward agreeing to that language you wrote, based on some good faith.

We can't do it any more. It's not there now. I can't agree to something in anticipation of a recommendation and implementation from committees that haven't begun their work. One of them's just barely begun its work. The Micro Committee is moving in a reasonable direction, but I'm not in a position, I can't go back to my organization and say, well, look, I went forward in good faith once and it turned out to have been a bad judgment. I can't do that a second

time, you know. Fool me once, shame on you. Fool me twice, shame on me, and I'm in that situation now.

DR. JOHNSON: But, Carol, I think the USDA is still taking even federal plants, they're still taking Salmonella samples and they're still taking actions based on the results of those samples.

MS. FOREMAN: That is the next issue on our agenda.

DR. JOHNSON: I agree.

MS. FOREMAN: And I don't believe that they are, and the Department has done two things. The Department refuses to enforce the Salmonella standard in plants not covered by Supreme Beef, and the Department has told the Congress it does not want additional authority to overcome the limitation that the court said is imposed by the 1967 Act.

I have no reason to believe in the good faith of the Department or the industry. I cannot go forward in support of interstate shipment of state-inspected meat in the absence of objective measures that the product coming out of the plant is equal to.

MS. KASTER: What if --

MS. DONLEY: Can I, please? I'd like to say something.

MS. KASTER: Okay. But I want to make one

point before that.

We're going to have this whole discussion after we hopefully come up with something down on a piece of paper here, and we're probably going to have to go the route of what Carol suggested, where we express under concerns some members, blah-blah-blah-blah. So, let's try to hold discussion about feelings on the Salmonella performance standards until the subsequent discussion and get this document finished up.

DR. JOHNSON: Could -- I just want to suggest some wording, based on what Carol just said, and I don't want to forget it. Is that okay?

MS. KASTER: No. Write it down.

MS. DONLEY: I've been waiting. I said it yesterday at the subcommittee meeting, and I'd like to have it on record today for the whole committee as well, is that, I was not in support of going forward with this either because the way that I said it at the subcommittee meeting was that frankly, we have a federal inspection system that I view as broken, and I see it as being a wrong movement to move forward with bringing a state-inspected product and giving it wider distribution to match a broken system to begin with. So, I just want to make that perfectly clear.

I also was the only one on the subcommittee that viewed the in recent events to mean the Supreme Beef case and the Salmonella performance standards. All my colleagues viewed it as the September 11th as being the recent events that would impact the interstate shipment.

That said, the idea of this was, just Carol so you understand as well, that we had put these things forward, that FSIS was given a charge that they had to go ahead and said under the resources what can you do?

I agree with you fully and would say -- and I like the idea of taking the pathogen reduction standard to have that as a point in and of itself, that there are members on this committee who, if that doesn't materialize, we will not support interstate shipping. Until and unless that happens, we will not support it.

MS. KASTER: Okay. Mike, you've had your card up for awhile, and let's hear what you have to say, and then Alice, we'll take your wording after that.

MR. GOVRO: I just had some wording as well, and that was to suggest that we write a sentence that says that consumer groups on the committee oppose extending interstate shipment to state programs until the Salmonella standard is established for all plants.

MS. DONLEY: I'd just like to ask, is it only the consumer groups? I mean, should we take a poll here? There might be some additional people. I'd be interested to know.

MS. KASTER: Okay. We're going to have Alice present some wording, and then, if you feel it's important that -- if somebody wants to come forward and add themselves as another grouping, if you will, then we can take a look at that.

Alice?

DR. JOHNSON: And Nancy, I apologize. I can't -- I don't remember things very well, and I thought Carol had put some wording that we just needed to slide right in there. So, Carol, help me with this. You talked about under Concerns, we can talk about performance standards and the need for objective measures to determine end product --

MS. KASTER: That products are the same level as federally-inspected --

DR. JOHNSON: Okay. That's -- yeah. Okay. So, if we did that, objective measure to determine products, would that work? Would that address your --

MS. FOREMAN: To determine that end products are --

DR. JOHNSON: Equal to or equivalent to.

MS. KASTER: At the same levels as federally-inspected product.

MS. FOREMAN: That's fine.

DR. JOHNSON: At the same level as federally-inspected --

MS. KASTER: As federally-inspected product. Okay.

MS. FOREMAN: I have some members of the committee do not support legislation allowing interstate shipment of state-inspected meat, unless there are objective measures -- unless the law includes objective measures to determine that state-inspected product is at least -- end products are at least equal to those being produced in federally-inspected plants.

MS. KASTER: Get all that, Moshe?

MS. FOREMAN: Does that make sense when you get it down on paper?

MS. KASTER: Yeah. Let's take a look at what it looks like on paper.

MR. GOVRO: Isn't -- is objective measures -- isn't that a little bit -- aren't we talking about something pretty specific here?

MS. FOREMAN: Well, I'm not prepared to say the Salmonella performance standard. I want a pathogen performance standard. Let me amend it to say pathogen

performance standard in mine.

MS. KASTER: Okay. So, instead of objective measures, it should say pathogen performance standard?

MS. FOREMAN: Objective measures, such as pathogen performance standard. That's better, isn't it?

MS. DONLEY: Carol, we had some other specifications in the prior draft. For instance, that the Secretary -- do you want to -- is that --

MS. KASTER: You're speaking of the 1997 draft, --

MS. DONLEY: Yes.

MS. KASTER: -- Nancy?

MS. DONLEY: Yes. Where we had specifically that there would be yearly audits, that there would -- the comprehensive review, yearly audits, the Secretary doing the actual -- the Secretary of Agriculture, the FS -- yeah. Federal inspectors doing the Salmonella testing and that the Secretary of Agriculture having the authority to hold product in the event that a recall was necessary.

MS. FOREMAN: Well, then the better way to do it might be to simply say that we don't support the passage of the legislation unless and until it includes the provisions incorporated by the committee in its

1997 resolution on this issue.

MS. KASTER: Okay. If we get to the point of writing something in where it says do not support the passage of legislation, then to me, we're going to have to go back the route of being more specific and naming a group that is relative to that as opposed to the wording that we have up here now is more general and might be supported by the entire committee or subcommittee. So, do you want to go that specific?

MS. FOREMAN: No.

MS. KASTER: I'm just asking the question.

MS. FOREMAN: No. I would go along with it, if it -- there's no antecedent to -- right now, it says the recommendations. However, the subcommittee felt that the following concerns should be considered during implementation. That's not a sufficient antecedent to the bullet that we have there.

DR. JOHNSON: Carol, if we --

MS. FOREMAN: We're saying Congress didn't ask us and FSIS didn't ask us about this. We're offering the opinion. We can't support it, unless Congress includes this when they enact the legislation.

DR. JOHNSON: Carol, if we reworded it to say concern should be considered prior to legislation or drafting of legislation -- or drafting legislation and

then make a recommendation that prior to moving forward on legislation, the committee has another review of it?

MS. FOREMAN: We wanted -- it has to be part of the legislation.

DR. JOHNSON: The following concerns should be considered.

DR. MORSE: Use the term "addressed" rather than "considered".

MS. KASTER: Yeah. It should be addressed in the legislation.

MS. FOREMAN: Yeah. It has to say in the legislation because otherwise this appears to be a directive to FSIS and that --

MS. KASTER: Okay. Then we're going to have to take out a couple things that we have listed under Concerns because we have food security, which I think we all agreed on, would be a guideline and which I had made a note to move up under Number 2 to include under the federal, and then the other one is, you know, obviously sustainability of state inspection programs and resources can't be incorporated into legislation. So, we almost need to --

MS. FOREMAN: It might be easier to make it a separate heading.

MS. KASTER: Yeah. And then put those

underneath there.

MS. FOREMAN: So that, the recommendations for Questions 1 and 2 would be A under Question 3 and B would be some reference to this issue. That way, you could keep all of your bullets that you have as 3-A and this would be 3-B.

MS. KASTER: Okay.

MS. FOREMAN: And we could go with -- I think I can go with that wording. I'm sorry. My eyesight's so bad, I can just barely see it. No. You leave that in, but the --

MS. KASTER: We leave that in.

MS. FOREMAN: -- bold face there, the recommendations, should be A, where it says the recommendations. That's 3-A. And then, what is now the last bullet is 3-B, except you --

MS. KASTER: I think we said -- that's where we said concerns addressed.

DR. JOHNSON: Can we change public health performance standards contain or -- and say which contains -- it doesn't read right for me.

MR. HOLMES: How about objective measures?

DR. JOHNSON: To say objective measures, such as pathogen performance standards.

MS. DONLEY: Inclusion of.

MS. FOREMAN: The inclusion of objective measures, such as pathogen performance standards.

MS. DONLEY: I would like to suggest it say the inclusion of objective measures, including -- I think the point, Carol, is we want a pathogen standard, pathogen reduction standard. So, not such as because we might just -- I think we want it known, at least I'd like it known that it contain a pathogen and/or other measures.

MS. FOREMAN: That would be okay with me.

MS. DONLEY: Inclusion of pathogen performance standards and other objective measures.

DR. JOHNSON: Okay. Then we need to -- not all the subcommittee, and I know this is our basic disagreement, but not all the subcommittee felt that way. If we're saying something like that, I want to have something to say, you know, scientifically grounded. Yeah.

MS. KASTER: And again, I think what we're trying to do is make it be consistent with whatever is federal. We're not saying that it should be more so for states, but Carol's big concern is that she feels that even though it's supposed to be right now, it isn't, but we're not saying that we're going to come up with some sort of new performance standards for the

states. It's going to be consistent with the federal, correct?

MS. FOREMAN: Don't knock out objective measures because --

MS. KASTER: I think he's moving it.

MS. FOREMAN: When you say scientifically-based, Alice, an objective measure is, I think, inherently -- to meet that standard, it would have to be based in science. I don't want those words in there.

DR. JOHNSON: Okay. Then let's figure out --

MS. FOREMAN: Just say objective -- you know, if it's an objective measure, then --

MS. KASTER: But objective could just mean Number 1, Number 2, Number 3. It doesn't mean how Number 1 has been determined. That goes back to it needs to be scientifically based which is, I think, consistent with what Dr. Murano's objectives are.

MS. FOREMAN: I understand. I understand, but they may not be the same as my objectives.

DR. JOHNSON: But I agree with whoever said we needed to be sure that we -- saying as safe as those coming from federally-inspected establishments, that makes it appear that we're not enforcing something on states that's not --

MS. FOREMAN: Right.

DR. JOHNSON: Should we say something consistent or -- I would like to have some kind of scientifically-based objective as defining objective measures or, you know, food safety objectives or something, some kind of wording like that.

MS. FOREMAN: No, not that phrase.

MR. LINK: Could we say pathogen performance standards consistent with federally-inspected facilities, which, you know, are -- I guess they're going to change after the scientific review, but they'll stay consistent with whatever they end up being.

MS. KASTER: Dr. Denton?

DR. DENTON: Thank you. No, that's okay. I am listening to this discussion with some interest and a great deal of concern about this. I want to go back and talk a little bit about some of the earlier points that have been made, particularly with regard to the Supreme Beef ruling.

There is something in doubt about the whole issue of performance standards, otherwise that court decision would not have been rendered in the manner that it was. As we look at the issues that this subcommittee identified that we think have to be

considered and have to be addressed, to me, what we've said under the performance standards that are currently under scientific review by the National Academy of Sciences' panel and the National Advisory Committee for Microbiological Criteria for Food satisfy that requirement.

What I think that we're trying to do here is enforce language in a piece of legislation that presupposes the outcome of the National Academy review and the National Advisory Committee review. I think that's presumptuous of us as a committee to take that position because I believe that we're presupposing that they're not going to recommend performance standards, and we have absolutely no way of knowing what the outcome of that particular review is, and I think if we're going to do this on a scientific basis, that we're going to have to stick at least until we get the outcome of those two reviews with the information that they're going to provide us and the agency.

We can get ahead of ourselves on this particular issue, and it makes me very uncomfortable to make a decision before we have a full set of information to make that decision on.

MS. SWACINA: Can I interject a couple of things here? First of all, we do have a commitment to

discuss the directive that I want to make sure we meet before lunch.

Second of all, do you all really need to have this in here? Since the whole idea, all we're doing is reviews.

MS. KASTER: I think everybody in this room can get comfortable with answers to Questions 1 and 2.

The problem is that the way that Question Number 3 is worded, it is worded very broadly. Does the committee have any additional concerns with the concept, and because that question was worded that way, all of these other things are getting pulled into there. So, I don't necessarily have a good suggestion on how to resolve it.

I feel like we can come up with language and corrections to Number 1 and Number 2, but I think we're --

MS. SWACINA: Do you want to go on?

MS. KASTER: -- going down the road with Number 3 that we could spend a long time talking about today.

MS. SWACINA: And we can spend a long time talking about the next one, too, our next topic. Do you all want to just drop Number 3?

MS. FOREMAN: I do not. I absolutely -- you

know, we got suckered into this in 1997. I'm not going to have it happen again. My organization will not tolerate me getting -- being part of this again.

Now, Jim, the Microbiological Advisory Committee has said the committee concluded that performance standards that meet the principles as outlined in this document are valuable and useful tools to define an expected level of control in one or more steps of the process, and then it goes on, incidentally, to say that in ground beef plants, that is also the fact.

The court said the 1967 Act does not include this. That's what the court said. The court didn't say it's written in stone, didn't say it's part of the 10 Commandments. We can rewrite the law. We're going to rewrite the law to allow state-inspected meat to move in interstate commerce.

I want to be sure that that also includes objective measures that some reasonable performance standard is included in that. It's okay with me if we have to say some members of the committee instead of the whole committee. We can probably do it faster if we do that.

Collette, I appreciate you and Alice trying to come up with some language that would make it

possible for everybody to sign on to. Linda's raised the issue that our time is getting short, and I'm prepared to settle for just saying some members of the committee, and it doesn't necessarily have to say the subcommittee. You can drop it down, make it a final point and say some members of the committee.

DR. JOHNSON: And I would wonder if we couldn't go back. Since this is just kind of a listing of concerns, if we need to go into this much detail, or if we -- the question asked, okay, is there any events lately that have caused you to think? We can say September 11th.

Nancy, I'll have to admit last night, I didn't think about that one, maybe because I'm too much into what's going on in D.C. The Supreme Beef case, that was what I thought might be a concern.

So, could we bullet point it like that and then, when we get another shot at this, and does that not raise the same issue without getting -- right now, I think we're really fighting over wording, and I wonder if we're just looking at the concerns. One of the concerns you guys have identified that's happened recently is the recent Supreme Court ruling.

MS. FOREMAN: Supreme Beef.

DR. JOHNSON: Supreme Beef.

MS. FOREMAN: Hm-hmm.

DR. JOHNSON: I'm sorry. I'm sorry. Would that address that these were the concerns mentioned, blah-blah-blah-blah, without going into --

MS. KASTER: I wonder if -- Moshe and I, I've got some notes down on Number 1 and Number 2. I think we've got the idea of what we're looking at in Number 3. I wonder if he and I can work on a draft and I don't know, Carol or Alice, if you guys want to do that over lunch, because once we see it on paper, we're going to talk about it again, and it's going to be hard to work up the wording here right now.

So, if we could do that, maybe we could stay with the time frame and then take a shot at making changes on paper.

DR. MORSE: Also look at the 1997 wording because that might --

MS. FOREMAN: That was Nancy's suggestion, is to go back and pick that up.

MS. KASTER: Does anybody have a problem with incorporating the 1997 wording from this committee? I mean, can that be a whole committee point?

MS. DONLEY: The whole committee came up with it last time just as a point.

MS. KASTER: Right. Mike?

MR. MAMMINGA: Well, it's kind of difficult for me to talk about this because I don't want to seem to be self-serving. So, I'm not going to do that. I'm going to tell you that we all have constituencies, and we all expound their concerns.

Sitting here and this is about all I'm going to say about it, I said yesterday, you set the standard. FSIS, the Congress, the President sign it. Set the standard. Let's get about doing it instead of talking about it. We've talked about it for 30 years.

So, in fact, it wasn't too long after the Act passed that they were talking about, gee, what about the state-inspected problem?

There isn't an issue here that hasn't been discussed a thousand times and another thousand issues you haven't thought of yesterday afternoon. The state program directors, as a group, are as diverse as this committee in the language, when you start wordsmithing what is to be done and what they'll support as a group.

I have a lot of feelings, but they're mine, and I will only observe this. Every issue that has been on this board is an issue that's relative to FSIS, except whatever particular things you're going to have the state do, but everything, including this last one about pathogen performance standards and scientifically

dah-dah-dah.

I feel as though the state programs are being held up as kind of a nice thing to dismantle in order to improve FSIS. That's how I feel about it. As though maybe it isn't polite -- well, we already take FSIS to task all the time anyway. So, maybe we'll have another venue for doing that by using the inadequacies of the state programs, real and perceived, and maybe ones we don't know yet.

This is really what issue? Food security, performance standards, sustainability. The Feds have a problem with money certainly. Every issue up there. We spent -- two subcommittees made recommendations about exposing and training and carrying, etc., etc., etc., etc. So, really, there's only a couple issues on that paper that are specifically directed at state programs. Otherwise, we're trying to improve FSIS.

My opinion, you can tell the state programs which has been discussed be like FSIS, apply their marks of inspection, adopt all their laws, rules and regulations, performance standards. If that's what you want, say that, make that the ultimatum. But I think we spent a lot of time working very hardly and diligently and creatively, perhaps as much on reinventing FSIS as we have the state programs and

that's all I have to say about that.

MS. KASTER: Okay. So, we'll do that. We'll work on some wording and see if we can't get to the end of this.

MS. FOREMAN: Thank you. Thank everybody.

MS. DONLEY: I just want to add one thing. I made the comment last night, frankly to Bryce. If there's been a cost-benefit analysis done on this, all of the time and energy and stuff that we've put in on this over the last couple years and all the stuff going on in Congress and the benefit to the industry, the little bit that they're going to -- it's -- this is -- it's ludicrous.

MS. SWACINA: So, the committee is going to work over lunch on final language, and so you want to come back after lunch with the language for everyone to react to? Okay. Okay.

All right. Let's move on. We have, I believe, -- Loren, I believe we need you up at the table. In trying to fit this in today, I just want to acknowledge up front that I think this will probably be a very unsatisfactory discussion due to the time limitations. I just want to say that up front. It's going to be difficult. We could probably talk about it all week. We'd still be unsatisfied, some of us would.

So, with the very limited amount of time we have, I want to try and be fair and give everyone on the committee an equal opportunity to talk after Phil gives his presentation.

So, I'm going to ask Phil to make his presentation on the document which, if we could go ahead and hand that out now, that would be great, and ask him to go no more than 10 minutes, maybe less, if he can, and then after he finishes that, everybody who wants to speak, if you could just put your name tag up, and then we'll just divide up the remaining time between those of you who want to speak, and if you have any questions, questions and answers will be included in the time, and I certainly will ask the responders to be very concise in their responses as well, and in fairness to everyone, no one should pass their time to anyone else because I want people who are very interested in this topic to be the ones who have the most time to speak on it, and we'll just go in order around the table, based on who wants to speak.

MS. FOREMAN: Excuse me. What is our time on this, Linda?

MS. SWACINA: We're going to go till 12:30. We'll push lunch back. We'll just take 45 minutes for lunch, although now that we're going to go with the

Committee Number 3 after lunch, -- well, we're a little more compressed.

MS. FOREMAN: We can fix it. I'm sure we can fix this language in a short period.

MS. SWACINA: Okay. So, does everyone understand that? Again, I think probably no one's happy with it, but I want to be fair and try and be fair to everyone and give everyone an opportunity.

MS. FOREMAN: So, I do want to be sure so that we don't get into a fuss later. If we have questions, we just raise our cards and you'll just start around the table?

MS. SWACINA: I'm going to ask after Phil finishes his presentation for everyone who wants to speak, hopefully you'll know after his presentation if you have questions or comments, if everyone will raise their flag at the same time, so we can count up how many people want to speak, and then we'll divide the time that we have. So, everyone will just get one opportunity to speak, and we'll just start again with Ms. Leech and go around the table for everyone who indicated that they wanted to speak.

MS. FOREMAN: Fine.

MR. DERFLER: Phil doesn't mean to disappoint, but I've invited Lee Purcelli from the

Regulations and Directives Development Staff to come and to walk you through quickly the draft notice.

So, Lee?

MR. PURCELLI: Okay. I just handed around the table a Draft FSIS Notice that will deal with the actions that we plan to take in establishments subject to Salmonella testing. This Notice has two major parts. First, it's providing instructions to program personnel with verification activities that they're to carry out upon receiving this Notice and slaughter operations subject to the Salmonella performance standards and in grinding operations that will be subject to Salmonella testing, and these activities will ensure that inspectors are properly performing verification activities with respect to establishment food safety systems.

The second part of the Notice sets out the steps that FSIS takes in response to failures of Salmonella sets. We'll discuss the first part, what we're instructing our inspectors to do when they receive this in slaughter operations.

Upon receipt of the Notice, we're instructing the SVMOs or IICs, where appropriate, to ensure that inspectors in the plant have carried out the appropriate procedures to ensure that establishments

have been meeting the regs and have procedures in place for E.coli procedures and that they are following those procedures.

On our next-scheduled PDIS task, we're going to have the SVMOs conduct an analysis of data generated from HACCP inspection findings for slaughter, raw not ground and raw ground products, and we're going to have them also look at the SSOP data, E.coli data and Salmonella performance data, and they're to determine and evaluate the relationships among these data and focus on trend identification and any links between the systems and also look at zero tolerance data.

On this report, the SVMOs will develop a report and it will be forwarded to the circuit supervisors with a cc to the district managers. To further ensure that all inspectors in establishments are following procedures, the circuit supervisors will take a look to make sure that the inspectors are performing appropriate E.coli procedures, sanitation procedures, HACCP 01 and 02 procedures, and sanitation performance standards procedures and that they draw relationships between all this data, and the circuit supervisor will provide that report to the district manager with a cc to headquarters.

Then for grinding operations, we're

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instructing the IICs to re-evaluate the establishment's sanitation SSOPs and to make sure that it meets the regulatory requirements and to focus on the facilities and equipment associated with the grinding.

The IICs will also ensure that the inspectors are verifying the SSOPs properly, that they are observing the establishments and monitoring the testing and sanitation conditions and are reviewing records, and then we'll have the IIC ask the same questions. Are they following SSOP procedures, the HACCP procedures, and the performance standards procedures? The IIC will send a document to the circuit supervisor and the district manager.

Okay. Then the second part of the Notice concentrates on the steps FSIS takes in response to set failures, and these procedures will replace the current procedures in FSIS Directive 10,010.1. That's the current enforcement directive. So, these procedures replace that and these procedures will apply in all establishments, grinding and slaughter, and first, we will no longer have the DMs call the inspectors in the establishments for them to write non-compliance records. Because of the food safety significance, we're just going to have the DM immediately write a letter to the establishments.

So, for a failure, the district manager will send a letter to the establishment informing them of the date of completion, the class of product and the results and include a statement telling them that the establishment needs to take immediate action to meet the standards.

The circuit supervisor and SVMO will conduct an assessment of the establishment's HACCP plan and SSOP procedures and analyze data where necessary or where appropriate for generic E.coli testing, and they will develop an implementation plan to verify any of the actions that the establishments take in response to the failure.

For B Set failure, the district manager again will send a letter to the establishment with all the information but this time include a statement that the establishment needs to reassess its HACCP plan and take appropriate and corrective and preventive actions. The district manager will consult with the circuit supervisor, the SVMO and inspection program personnel to determine whether the establishment has conducted an acceptable reassessment and has taken the appropriate corrective actions. If not, at that time, the district manager would issue a Notice of Intended Enforcement Action, known as NOIEA, as set out in the Rules of

Practice.

After the reassessment and appropriate actions are taken, the district manager will initiate an in-depth verification review set out in the Directive 5500.1 and a consumer safety officer will be a part of that team.

The district manager will receive the report from the IDV that will contain the team's findings. The district manager will have the inspection coordinator analyze the findings and make recommendations about how to proceed. It's important to note that before proceeding with follow-up sets, the C Set, the DM is to have a high confidence level based on the analysis that the establishment's food safety systems are now controlling production.

There are three decisions the DM is going to make, based on this analysis. They could determine that, based on the analysis, that the food safety systems are not meeting a regulatory requirement. In that case, an NOIEA would be sent out. They could also determine that the food safety systems are not adequate but this is because of design or execution problems and not specific regulatory non-compliances. In this case, the DM will send the IDV to the establishment along with a 30-day letter outlining the specific concerns

and requesting that the establishment perform a new reassessment or they could determine that everything is fine now and that a C set will be scheduled.

Again, based on anything that the establishments do in response to the failures and the corrective actions and the IDV, the CSO will take the lead in developing verification procedures that inspectors will carry out in the plant and the circuit supervisor will monitor and send reports to the district managers.

In the case of a C set failure, again the district manager will send a letter to the establishment and will inform the establishment that FSIS will instruct a CSO and a compliance officer to conduct a focused assessment of the establishment's food safety systems to investigate why in the light of previous reassessments and corrective actions, the establishment failed the C set. For a slaughter operation, the DM will immediately consult the headquarters.

The CSO and CO will focus their assessment on the reassessments and corrective actions taken after the B set failure and will determine whether the food safety systems are adequately preventing food safety hazards. Also, at this point, emphasize, may decide to

conduct IDVs at the establishment's suppliers.

Based on the findings of the CSO and the CO, the DM and headquarters officials will determine what actions to take. Failure on the part of the establishment to prevent or eliminate or reduce to acceptable level food safety hazards will result in enforcement actions, and there may be rare cases where the CSO and CO finds that additional reassessments are necessary, and in such cases, the DM would issue a 30-day letter and all the follow-up verification procedures as discussed before would occur.

That's basically what the Notice will be instructing to our field personnel.

MS. SWACINA: Okay. If everybody who wants to ask a question or comment on this could raise their cards so we can count this up and divide the time? Okay. 1-2-3. Three people?

MR. HOLMES: I'm not sure.

MS. SWACINA: Speak now.

MS. FOREMAN: You can always give it up later.

MS. SWACINA: That's right.

MR. HOLMES: At the end.

MS. SWACINA: I can't -- no. I'm going to start here. Go that way.

MR. HOLMES: Take mine down.

MS. SWACINA: Okay. Four. Okay. So, that's five minutes apiece, right? Does that take us to 12:30? Charlie's timekeeper.

MS. KASTER: Just a clarification to what you're doing. I mean, obviously there's going to be other comments and discussion that arise from that. So, I mean, you're not precluding the rest of us from talking?

MS. SWACINA: Yes, I am.

MS. KASTER: Okay.

MS. SWACINA: Your opportunity to talk is only if you have your card up. Let me clarify that.

MS. KASTER: Okay.

MS. SWACINA: Because we have a very limited amount of time, and I want to try and be fair to everyone. So, if you want to comment, please let me know now. Okay. We'll go with five minutes apiece, and it's Dr. Denton, Ms. Foreman, Ms. Donley and Dr. Johnson. Charlie, yes, will tap his glass when your time is up.

So, Dr. Denton?

DR. DENTON: As I look -- pardon me. I suppose I need the microphone here. My voice might carry that far.

As I look at this, it appears to be a very reasonable approach. In looking at the C set failure, there appears to be some effort to move back into the establishment's suppliers as the primary point of focus on a C set failure. Am I interpreting that correctly?

MR. DERFLER: I don't think it's the primary point of focus. It's a potential point of focus.

DR. DENTON: Okay.

MS. SWACINA: That was it? All right.

MS. FOREMAN: Okay. Let me try to organize my questions here and see if I can get them.

First of all, I want to ask a more general question. Are there still the delays occurring between sample -- during sample sets that are reported in this hamburger hell study where you have sometimes hundreds of days between -- before a sample set is completed?

MR. LANGE: Yes, we certainly -- we have a list of establishments we're working on where we have sets that have been on-going for a fair length of time.

In February, we sent out a list under Dr. Master's signature and OFO to sort of, you know, either find out has the product -- has production stopped in these sets? Is it a question of the IIC ran out of sample forms and we didn't get additional sample collection forms to the plant, and I was looking at

this just yesterday.

I think about a half of those, we have closed out since then, and we've redone it, and, of course, we got more on the list, but we certainly -- we're discussing that right now. We don't -- you know, we don't have in Washington anyone sort of that -- staff or resources dedicated to try to, you know, follow up on all these sets that aren't completed. We do send out periodically, you know, what we call our non-responders report.

We have an -- in the automated system that we call PREP, Pathogen Reduction Enforcement Program, we have --

MS. SWACINA: Loren? Loren?

MR. LANGE: Yes?

MS. SWACINA: I just want to remind you to be concise.

MR. LANGE: Oh, okay. I mean, we're --

MS. SWACINA: The answer was yes.

MR. LANGE: Right now, we're doing everything we can, but there are still some, yes. I forgot about the time.

MS. FOREMAN: Okay. What is the maximum length of time that might transpire -- incidentally, the Micro Committee urged you to let plants know

immediately when they've failed six tests. So, I'm not alone in urging that somehow there be some notice and people move through this faster.

Is there -- what's the maximum length of time that can pass between the time that a plant fails an A set and a decision is made to do a second set of tests and the maximum that can pass between a failure of a second test and the taking of a third test?

MR. DERFLER: I don't think there's a maximum amount of time. I think we tried to make the decision as expeditiously as possible in accordance with what's laid out here and then we move on.

MS. FOREMAN: So, if I decide I ain't going to do it, you're not going to take any action to force me to do it. If I decide I'm going to stand on one foot and stall, --

MR. DERFLER: The I being the district manager?

MS. FOREMAN: If a plant decides -- fails the first test and decides when the IDV comes in they're going to drag their feet till the end of time, what happens? You're just going to let them keep doing that? Isn't there some limit?

MR. SMITH: No, there is not a time limit. We will act. The first set, you would not have an IDV.

The first set, they have to initiate corrective and preventive actions. If they fail to do that, we would act under the Rules of Practice at that point which would be issue a Notice of Intended Enforcement. They have three days to respond to that, and if they don't respond with corrective and preventive action, we would suspend the inspection.

MS. FOREMAN: But what's the period --

MR. SMITH: On the second set, --

MS. FOREMAN: -- of time? I'm sorry, Bill. But my time's limited. What's the period of time between the time that the IDV comes in and you begin to write a letter of intended enforcement?

MR. SMITH: Okay. On the IDV, if -- usually we try and get the IDV out within two weeks of conducting the IDV. If we have non-compliance, we'll issue the letter right then, and they have three days to respond. If we have questions about the scientific design, they have 30 days, and at the end of 30 days, then we make the decision to take enforcement action or not.

MS. FOREMAN: In Supreme Beef, it went on from about February -- almost a year before a third set was taken and that was when you're really enforcing it.

Is there any way that you can make some

specific time limits on these things, so that the public will have some feeling that there's action taking place?

MR. LANGE: In the very beginning, we sort of -- some of us were a little naive when we put that initial directive and we put those time limits of 30 -- suggested time limits, and then one of the first times when an establishment had failed a set, they came back and wanted to do major construction and putting in a steam pasteurization system. They laid out a time frame of getting corporate approval and construction, and it was a long time, but I think everybody felt at that time that was -- it was an appropriate response, but we had to allow for that. So, that sort of complicated, you know, some of our sort of early thinking on what the time takes.

MS. FOREMAN: Now that you know, can you not set some time limits on this or should the public expect that somebody --

MS. SWACINA: I'm sorry. Time is up. Sorry.

MS. FOREMAN: -- is recalcitrant, will just be allowed to continue?

MR. SMITH: We will act just like we do with any -- we have been. If we have -- we identify the plant needs to do corrective and preventive action, we

expect response, especially of non-compliance, we expect immediate, that's anybody's decision whether immediate's one day, one hour or three days, but we're not talking extended periods of time till we will make a decision whether to enact the Rules of Practice or not, and we have been consistent in doing that.

MS. SWACINA: Okay. Ms. Donley?

MS. DONLEY: Carol asked the questions and concerns that I have. I think this open-ended policy is just -- is disastrous.

Question. With some of these plants, what other measures are you thinking of taking in the interim while they continue to fail sets? For instance, will you target plants that are in a -- who have been failing their first sample set? Have you thought about targeting them for 0157 testing? What about other increased inspection, increased SSOP inspection? Can you respond to that?

MR. DERFLER: The answer's no. This is verification testing. We have the inspectors in the plant. They will continue to perform in accordance with the assignments that they get.

To answer the other question, none of these plants go unmonitored. If they fail a set, they're on the district manager's watch and they're on our watch

in Washington, and they're not just left to float.

MS. DONLEY: What about, though -- I think if -- does FSIS -- can you or do you have the ability to go in and say we're going to -- I know that the -- instead of just doing the typical number of SSOP checks, to step it up, to take a look at it, and obviously the plant's having problems, and so maybe we need to be doing -- looking at additional things to help them out.

MR. DERFLER: Two things. I mean, the IDV when it's ultimately done is done in part to help the plant out, but the other thing is, if we're finding a problem, then we'll issue an NOIE. We're not going to continue to let them go along or wait for another set. If there's a problem that's inconsistent with our regulations, we will act, and we will issue an NOIE.

MS. DONLEY: And so, does that mean -- I'm not understanding completely what an NOIE is.

MR. DERFLER: I'm sorry. It's a Notice of Intended Enforcement Action which means that they have three days, and if they don't give us an adequate response in three days, they're suspended.

MS. DONLEY: What's considered an adequate response? We're working on it?

MR. SMITH: No. They would have to

demonstrate scientifically and with validated data that they have addressed the problem.

MS. DONLEY: And does that -- can that get done after a sixth positive sample or I don't understand why the -- why do you have to wait for an NOIE until after the sample set is completed. Is there some way we can issue that earlier?

MR. SMITH: Again, we got to go back to the regulations. We touched on this real briefly. We have three sets, and as Phil said, this is on-going verification. It does not mean they're out of compliance on the first set failure, the second set failure. What it does tell us is we have information that says we need to go back and look at the validity of that system and so that's why we're acting after the first set. We're asking them to go back and look at that. After the second set, we have said you must reassess and then we'll make regulatory decisions on that and that's what we've been consistently doing lately.

MS. DONLEY: I just wish the public had as many chances to, you know, dodge the bullet as the companies do with contaminated product.

MR. LANGE: The one thing that's important to remember, though, if a plant fails and is operating

actually -- well, the plant that's operating at the performance standard does have a 20-percent chance of failing, even though they are meeting the standard, the way the system is set up, and early on, that's why the decision was made to complete the A and B sets because we felt it was important to find out whether they failed right at the one over C plus one or that they had two C plus ones. So, we considered that very important because there is that probability. We set that relatively low, that the 80-percent numbers, so that there's --

MS. DONLEY: Right. And Linda, I'm sure my time is up, but -- oh, it's not. Okay. I just can't stress enough to the agency that, you know, you guys are doing the best you can, I hope, but we're dependent on you then to come up with creative ways that with your hands being tied the way that they are right now, we want you to come up with creative ways to help to better protect the public and that's why I'm throwing out some of these other suggestions here, and I'm sure you all can come up with much better ideas than I can, but, you know, we want to give you back your enforcement tools, and it makes me crazy that the companies get little slaps on the wrist and you can't just say hey, you're down. So, anyway, please work on

that.

MS. SWACINA: Thank you.

MS. FOREMAN: Linda, the time is not up, but you've taken all the cards. Can we --

MS. SWACINA: Sorry? Alice is up.

MS. FOREMAN: Oh, I'm sorry. I didn't see your card up.

DR. JOHNSON: I put it down because I thought everybody --

MS. SWACINA: Okay. Dr. Johnson?

DR. JOHNSON: Thanks.

And I don't want to take up much of our time, but I do want to thank the agency and everybody around the table for the way -- I think this has been handled very well, letting everybody have their turn and keeping things focused and organized. So, I do appreciate that.

I have a couple of questions for Bill and Loren. NOIEs, Notice of Intended Enforcements, 72 hours, you go down. Have you issued any of those for sanitary conditions related to what goes on in a plant on a day-to-day basis without there being a sampling failure?

MR. SMITH: Yes.

DR. JOHNSON: How many?

MR. SMITH: Yes. Oh, I --

DR. JOHNSON: You've got inspectors in the plant every day, and there's nothing that -- I know you now have consumer safety officers. They're going in the plants and so there's nothing that keeps anybody if unsanitary conditions are found in a facility from making the appropriate determination as to whether there's a need for an NOIE.

MR. SMITH: Right. Well, there's two things there. If you walk -- if you have unsatisfactory sanitary conditions, you don't even have to issue a notice. You can suspend immediately.

DR. JOHNSON: And that's made at the in-plant level by the inspector that's there all the time?

MR. SMITH: Yes.

DR. JOHNSON: They can stop operations?

MR. SMITH: Yes.

DR. JOHNSON: I have a couple of comments, based on this time frame with sampling, and I do think it's important that -- I know I have members and having worked on the other side of the fence, I've done it. If you see problems, you have the authority as an FSIS inspector to stop operations, and I have member companies that call all the time going, hey, Alice, we're down, what do we need to do?

I think that nobody opposes pathogen reduction. Everybody supports reducing pathogens. In order to accomplish that, sometimes you have to do some pretty extreme measures. I know of some slaughter facilities in which they've gone out and tried to work on, and this is broiler and turkeys, they've gone out and tried to do some things in the field, and in order to do that, if you're talking turkeys, if you do something in the poults as they're coming in, you vaccinate the birds, it's going to be eight weeks to 20 weeks before you can see if you have any results, and I think that a company that is sincerely working at that level, you talked about major construction going in at the facilities, you know, people are paying a lot of money and doing a lot of things, and I respect that the agency is looking at this and making a determination of who's acting in good faith and who isn't, and I think that's something you need to really keep in mind, that companies that are moving forward and trying to do things should be given the opportunity to let whatever interventions they're trying to take work through the system.

Again, you've got the right to handle unsanitary conditions in any manner you feel appropriate, based on what goes on in the plant.

I do think that the in-depth verifications that Bill was talking about, as painful as those things are to industry, really get to the heart of what we're all about and that's food safety and what companies are actually doing, and I know that there have been some IDVs performed in which 72-hour letters, NOIEs, have been issued after the IDV. The IDV goes in, it looks at the scientific justification. It goes into exhaustive detail on do you have the science to support what you said you've done, and then they go out there and with a finetooth comb, they observe the facility to see if what they've said they're doing in their plan they're actually doing, and yeah, there's no way a company can work around that. You're either there or you're not, and I think that's an excellent way to look at the product and the safety of that product coming out of the plant, and it really gets to the heart of the matter and the scientific justification behind it.

I also know that when they're in that plant conducting an IDV, if there's problems in that plant, they don't wait two weeks for the report to come out. They're corrected immediately one way or another. So, I think the agency still has a lot of authority.

I also want to comment on the whole -- the directive, having just seen it, I think there may be

some issues there, but I don't want to comment on them because I haven't had time to really absorb them and probably couldn't do it in just five minutes, but I do encourage the agency, you've got some good scientific reviews being carried forward, and I think you should push that those reviews be concluded as quickly as possible and that some determinations be made based on those reviews and any type of revisions or new regulations that are justified, based on the outcome of the panels, be incorporated and moved forward and given priority to get through as quick as possible.

With that, I'll conclude. Thank you.

MS. FOREMAN: We still have a little time left till 12:30.

MS. SWACINA: Dr. Murano wanted to make a statement.

MS. FOREMAN: Well, let me just ask. I'd be glad to split it with Alice, but I would like to say something else.

MS. SWACINA: Let Dr. Murano speak first.

DR. MURANO: Go ahead.

MS. FOREMAN: Thank you.

DR. MURANO: Just give me two minutes.

MS. FOREMAN: I appreciate it.

There's a different perspective here that

Alice and I have reflected or that I'm about to reflect. The question is whether, since all meat and poultry products come to the public with a stamp on it that says USDA inspected and approved, there is an obligation to meet a standard quickly or does USDA have an obligation to keep people in business? I think it's the first.

I would feel much better about this Notice of Intended Enforcement, except that I'm looking at the enforcement records most recently published on your website and page after page after page says enforcement action was deferred, plant previously received a Notice of Intended Enforcement, remains in abeyance, plant previously received a Notice of Intended Enforcement. Again and again and again, those same words. Some of those things go on for a year, some of them go for over a year.

What does that mean? What does it mean? You've got an enforcement but nobody's taking any action on it.

MR. DERFLER: That's not true. What it means is the plant received a Notice of Intended Enforcement Action and they came through with a corrective action plan that the district manager found to be acceptable and on that basis, the district manager deferred

enforcement action.

MR. SMITH: And we are tailoring inspection

--

MS. FOREMAN: But it doesn't say it's closed.

It says it's in abeyance, which means that you haven't decided that it's okay.

MR. SMITH: We have tailored inspections to verify that the things they put in place are being done over time, and that's why they've been placed -- deferred or placed in abeyance, and typically we do not have those going past 90 days anymore. Early actions.

We did have some going longer, but typically six months is an old action at this point.

We set that standard with the district managers, that we want them to make a decision either things are corrected or reinstitute the action.

DR. JOHNSON: Can I just ask one question real quick to Bill? Is it -- Bill, when you get the letter of intended enforcement, the 72-hour, you don't automatically -- a lot of these plants are shut down for a day or two while they develop their corrective actions, and it's my understanding the abeyance is just you let them start operating to get some data for the fact that their corrective actions are actually appropriate. So, it's more of an intensified

inspection but they maybe have had -- I know I've been through a couple of these where there have been down times for a couple of days while the plant reviewed and did their corrective action and submitted waiting for decision and that's when you go in abeyance after you determine it's appropriate and you wait to see if the plant will actually carry out what they say they were going to do.

MR. SMITH: Yeah. I just want to be clear on your scenario, though, that if there's non-compliance, the reason the plant is down is because we've taken official control action to stop the operation, to not apply the marks of inspection, and it is during that time that they proffer their corrective and preventive action, but the decision to put an abeyance is based solely on that and that the reason that the official control action was taken has now been eliminated.

DR. JOHNSON: Thank you.

MS. SWACINA: Again, I do want to say thank you to everyone and apologize again for limiting time. I know it's unsatisfactory to do this.

I do want to remind everyone that we are planning a public meeting on performance standards in January and hopefully -- well, we're expecting at that time to have the NAS results, and so we'll be able to

discuss them as well.

So, I will let Dr. Murano close it out, although I will just say, if everyone could be back promptly at 1:15 from lunch, and we'll start off with the Subcommittee Number 3 final, hopefully, document.

So, Dr. Murano?

DR. MURANO: Thank you very much.

As you predicted very well, this would not be satisfactory in terms of time. There's a lot of people who have a lot to say, and it's understandable. So, it was going to be a frustrating experience from the get-go. So, you predicted it very well.

I just want to say a couple of things. One is, whether folks realize it or not, this directive that was just reviewed very, very quickly, unfortunately, and without enough time or adequate time to explain all the nuances, etc., this is stricter than was being done before the Supreme Beef decision, and I think everybody here knows that. This is stricter. No time before were IDVs done, no time before were IDVs considered of suppliers. I hope people realize that. We're doing things after the first set failure.

The second thing I want to say is that I have asked this question of the professionals at this table. What happens -- and a very good question that Nancy

asked. What happens after six positives, if you will?

It's wrong to wait until the 51st test that's taken to inform a plant that things are not going well.

Absolutely, it is wrong, and I'm told by my folks over here that there is a verbal communication with plants.

There is verbal communication that says, you know, yes, testing's going along but you guys better start looking at what's happening in the plant because it's not going well.

We're doing that for the purpose of trying to protect the public's health to the greatest extent that we can, and we can't protect the public if we're waiting until test results are in obviously.

The third thing I want to say is that we've talked about what is done during this time that plants are reassessing their HACCP plans and so forth. We are there still every day. We have two excellent inspectors-in-charge back in that back table over there who have put up with all the presentations and all the time here. I'm sure they'd rather be somewhere else. No, you'd rather be here, huh? Okay.

I asked the two of them a very important question yesterday. I asked them, what would happen at your plant if you had a second set failure, and they said, well, we haven't had that experience, but we can

tell you that we would, of course, step up our verification. The things that we can do, we would focus our scrutiny and intensify it because we know these people are about to suffer big time consequences, and we want to make sure that if they're implementing changes, that they are changes that make sense to us as professionals, and these folks are veterinarians. They're not uneducated people.

So, those things are happening, and the last thing that I want to say is that, you know, when we talk about having an objective measure, we have an objective measure right now. We continue to test for Salmonella, and we use it as an objective measure to point us to what is going on in the plant in terms of HACCP or sanitation operating procedures not being done adequately or not being scientifically sound. That's why we have consumer safety officers, by the way.

Never before did FSIS, to my knowledge, actually go in and look at the validity, the scientific validity of HACCP plans, and we do that now with consumer safety officers. It's not a perfect system, believe me. I've been at this job seven months, and I cannot expect to fix something that's been -- that's had problems for years in seven months, but we've made tremendous strides in my opinion, and our inspectors

don't shy away from their duties of verifying what's going on in the plant, in spite of Supreme Beef or not.

We've had many NRS issued after the Supreme Beef decision. We have shut down plants after the Supreme Beef decision and continue to do so, and not only, as Phil said very well, are these matters brought up to the attention of the district manager and his or her watchful eye, comes up to headquarters attention and it comes up to my attention. We have meetings every week where these subjects are discussed. What plants are on the verge of failing? What plants are in trouble? What are we doing?

So, I assure everybody here that every effort is being expended to make sure that we protect the public's health because that is our Number 1 priority and that's all I wanted to say.

Thank you.

MS. SWACINA: See you at 1:15.

(Whereupon, at 12:35 p.m., the meeting was recessed, to reconvene this same day, Thursday, June 6th, 2002, at 1:15 p.m.)

## A F T E R N O O N      S E S S I O N

1:26 p.m.

MS. SWACINA: Does anyone know if -- is Dr. Morse still here? Did he have to leave? Does anyone know? He's still here. Okay. And who else is here? Mr. Link?

MS. FOREMAN: Link's here.

MS. SWACINA: He's around.

DR. JOHNSON: Yeah. He's coming.

MS. SWACINA: We do know he left. Okay.

Okay.

Before we move on to Subcommittee Number 3, I want to just take a couple minutes and circle back on HIMP because I really wanted to let everyone know that we've really taken all of your comments yesterday on HIMP to heart, and it was frustrating yesterday to hear many of the questions that you've previously raised be raised again, and the agency still is unable to provide answers that satisfy you and that's not acceptable.

We need to go back in the agency and take a fresh look at HIMP. We need to look at the data to see if it's adequate, just needs to be communicated differently, or if there really is a fatal flaw with the data.

We believe the goals of the program are sound

but that's not worth anything if the public isn't assured of adequate food safety under the program. We will not make a decision about rulemaking until we can conduct a peer review and we can ascertain that it's prudent to go forward as per the peer review, and we will not move forward with the contract for peer review until we re-examine the data internally.

I want to thank you all very much for your input yesterday on HIMP. It really was very helpful, and it was helpful in assuring that we take another look at this program.

Okay. Are we ready to do Subcommittee Number 3?

MS. KASTER: Yeah. All right. Several of us worked through this and as soon as we get that up on screen, we decided to go that route rather than print and revise and print again, and so I appreciate Moshe's help and hope that he'll keep me straight as well as anybody else on the changes that we made.

I'll go ahead and mention the first change before -- there we go. The first change is under Numbered Question 1 where the point came up about 1999 versus 2000. We changed that wording. It now says, "Recommend that FSIS review back as far as 2000 all state comprehensive reviews that have been completed",

etc., etc.

Then because we knew that that would kick it into a pretty restrictive time frame, we strengthened the wording underneath and that now says, "Because the time frame is probably too restrictive, additional funding and an extension for the due date of the report to Congress should be pursued", then mentions out of source contracting as a possible option.

Are there any concerns or changes to the language under Question Number 1?

(No response)

MS. KASTER: Good. Okay. Under Question Number 2, as a group, we had already decided to add the final bullet point which is the part about state inspection personnel participate in FSIS field force training. The other thing that we did was move the mention of food security guidelines up from Question Number 3 to Question Number 2.

So that, now underneath the part where it says, "Request states to adopt all federal food safety regulations", etc., that underneath, it says, "Food Security Guidelines be considered", so that it's considered for states as well as federal.

Any issues with that section?

(No response)

MS. KASTER: Good. Okay. Question Number 3.

We had started going down the road of dividing this question into two parts, and Nancy, Alice and Carol stayed back and worked on language and then some other people were here and reviewed that.

What we did was take that out of being a separate bullet point. So, the first two bullet points have not changed. Sustainability of the inspection programs and exposure to federal inspection meetings. The third bullet point is what -- is our attempt to capture the discussion that we had and that bullet point reads, "Some members of the committee stated", and I guess we'll need to put a "they" in there, Moshe, "they will not support" -- sorry. I was reading. Thank you.

"... stated they will not support interstate shipment unless the Secretary has the authority to enforce pathogen reduction performance standards in meat and poultry products."

We have language everyone can live with?

MS. DONLEY: Just one really minor point. Do we want to say, however, the subcommittee or do we just want to say the committee?

MS. KASTER: We need to say the full committee, I believe.

MS. DONLEY: Yeah.

MS. KASTER: Okay. Good. All right. Any other questions, comments? Going, going, gone. Thanks, everybody, for their input on that.

MS. SWACINA: Great. Thank you. Okay.

Is there anything else we need to talk about before we move on to our presentation?

(No response)

MS. SWACINA: Okay. Our first presentation for the afternoon is on the Overtime Rate Structure Study and that will be given by Jeanne Axtell, who is our Acting Deputy Administrator for the Office of Management.

Briefing - Overtime Rate Structure Study

MS. AXTELL: Thank you, Linda, and I appreciate the opportunity to come and meet with the committee and brief you on the current state of the Overtime Rate Structure Study.

I do not have a handout, other than the one that is behind Tab 7, and I'm basically going to be following pretty much the outline of what is in your briefing papers, in the discussion, and so there's not an overhead. So, if you want to turn to Page 7 or Tab 7, that would probably -- is it 8? I apologize. Thank you. Tab 8.

In the development of the President's budget for 2003, OMB requested that the agency engage in a study of its current overtime rate structure with the aim of looking at modifying that rate structure in FY 2004 as a part of the budget formulation process for that fiscal year's budget, and we will be engaging in the development of that budget for 2004 over the next few months.

OMB's interest particularly in this was to assure that the agency took a look at the effects of its current overtime rate structure and the distribution of both the costs and benefits across various sectors of the regulated industry.

While there have been many examinations of the overtime rate structure in years past, there has not been one conducted since HACCP had been implemented and that took into consideration an examination of the costs and benefits around looking at the regulated industry based on size in the manner in which we presently do under the HACCP system, and by that specifically, I mean, looking at the costs that are paid by large plants versus small plants versus very small plants, based on the definitions that are in our regulations currently for large, small and very small plants.

There has been a concern for some time that there are inequities built into the present overtime rate structure that cause the smaller plants, generally the small and very small plants, to pay disproportionately larger shares of the costs of overtime inspection services provided by FSIS to the industry than do the larger plants, and so to basically take a look at this issue again, OMB asked that we undertake this particular study.

As a part of this study, we also have been asked to look at various alternative rate structures that might be examined and alternative cost-sharing proposals that might be contemplated between the Federal Government and the regulated industry over providing for the costs of inspection service.

Basically, as we're undertaking the study at this particular time, we have subdivided it into three phases. The first phase, which is the one we are engaged in at the moment, is basically a descriptive phase in which we are taking the data from FY 2001, which is the last full year for which there is data, and basically profiling of those establishments that we regulate what categories they're in in terms of large, small and very small, and then examining the costs of overtime inspection services which are billed to those

industry sectors and to further describe that data by looking at each of the various sectors, large, small and very small, in terms of those plants that have only a single shift and those plants that have two shifts of inspection work being conducted for them.

The basic theorem that OMB has been examining here or the concern has been that large plants, because of the economies of scale that they are able to employ in their production activities and the fact that they can operate two shifts, that they in effect are receiving a benefit from FSIS in terms of the free inspection services associated with a second full shift of operations. Smaller plants, lacking perhaps those same economies of scale, who cannot operate full second shifts, are paying for inspection services on an overtime basis for services beyond one shift of operation.

So, in Phase 1, we're basically taking the data. We're reassembling it. We're drilling down and looking at the data in a different kind of way than we presently -- than we have for some time and categorizing the plants again by large, small and very small, by first and second shift operations, and then looking at which of those sectors then contribute -- what dollars they are contributing to the overall

revenue which the agency obtains as a result of the overtime charges it places on the industry.

In the second phase, we will then move to looking at various cost-sharing proposals that specifically OMB has asked us to look at. In particular, this would mean looking at what the effects might be if all regulated industry members were charged for overtime beyond eight hours of inspection service per plant. So that, in effect, the taxpayer dollars that come to the agency for purposes of conducting inspection would basically go to support eight hours of inspection per plant and anything beyond that would be at the expense of the regulated industry member.

That's the first part of the proposal that OMB has asked us to look at.

The second part of the proposal would then be to say that for those hours that would now be subject to overtime charges, in other words, anything beyond eight hours per day, to look at various cost-sharing alternatives that might be considered. Specifically, what -- how that might -- how the distribution of the costs and benefits across large, small and very small plants might change if that overtime cost was shared on a 50/50 basis with the industry as opposed to a 100-percent basis by the industry, and then we will likely

look at some cost-sharing proposal in between, a 50/50 share and a 100-percent share.

It is anticipated that in that process, the actual rate charged per hour of inspection service might possibly be lowered and so we will also as a part of that look at what adjustments in that rate might look like and what then the distribution of the costs might be as a result of a lower set of rates applied in a different manner across the various sectors.

We may be somewhat limited in the range of options that we will need to look at because a basic premise under which our overtime inspection services and our rates are developed for purposes of charging a rate to the industry is a rate that's based on what is called full cost recovery, and whatever we're looking at, we will need to fully recover the costs associated with the inspection service to the agency but then subsequently would be looking at some alternatives for cost-sharing between FSIS and the regulated industry.

The third part of this study that we have been asked to look at specifically would be the possibility of considering a licensing fee to be applied on an annual basis to all members of the regulated industry having a grant of inspection.

It has been characterized to us as not unlike

a licensing fee that some states apply for purposes of allowing a business to be in business or not unlike a licensing fee that most of us have for having the privilege of being able to drive our automobiles.

So, the notion would be that as we proceed through the study, it moves from initially in Phase 1, a general description of what the current state is, looking at the various sectors of the industry and the distribution of costs and benefits across the sectors, to Phase 2, where we begin to look at various proposals that might involve changing who pays for what beyond eight hours of inspection service and then subsequently in Phase 3 looking at the possibility of some type of licensing fee.

Essentially, that is the scope of the study that OMB has asked that we conduct as a basis of input to subsequently inform the formulation project process for development of the 2004 budget for the agency, and I'd be happy to entertain any questions.

MS. SWACINA: Thanks, Jeanne.

Mr. Holmes?

MR. HOLMES: Marty Holmes, North American Meat Processors.

Jeanne, do you have information on what -- and maybe this study -- I'm just curious off the top of

my head -- off the top of your head. The rate that the agency charges roughly percentage-wise, what part of that goes to the inspector versus to the administration for overhead? Do you know?

MS. AXTELL: I don't recall off the top of my head. The bulk of the rate is for direct -- the providing of direct inspection service at the plants. There is a portion of that rate that is associated with administration and overhead costs of the agency that is distributed as a part of that rate. I can get that information for the committee, if they wish.

MR. HOLMES: I think it'd be interesting to have. If I recall, and I mean, this has been years ago, that the majority of that dollar was actually going back to the -- to cover administration. Now, I'm talking about versus what's actually going into the pocket of the inspector.

MS. AXTELL: Actually, there -- the methodology by which we developed the overtime rate itself, Marty, we actually contracted with an outside firm some years ago to assure that the methodology we were using to develop the rate was consistent with various statutory requirements associated with how government entities, Federal Government in particular, is expected to go about full recovery of its costs for

the providing of a service.

After those methodologies were developed, they have been reviewed during various audits that have been conducted by the Office of Inspector General, associated with the annual consolidated financial statement reviews that the IG's office does of financial statements of the Department.

So, they have both been developed with the input of outside parties and reviewed by appropriate oversight agencies to assure that they are consistent with current statutory requirements, and we'll be happy to provide, you know, some information on that.

MR. HOLMES: One of the other things that comes to mind and we've talked about this cost-benefit ratio, I'm curious. Does that ratio in any way reflect the risk of the process being inspected?

MS. AXTELL: No, it does not.

MR. HOLMES: Okay.

MS. AXTELL: At the present time, because it -- at the present time, the current overtime rates really take into consideration literally the costs associated with providing the service. So, it's looking at the population of inspection program personnel, the numbers of them at various grades who are involved in the conduct of overtime services at the

plants, and calculating what those direct costs are and then seeking a rate that, on a per-hour basis, permits recovery of that.

MR. HOLMES: Okay.

MS. AXTELL: It does occur -- include projections for salary increases, etc., but done in a manner consistent with established ways in which you estimate for those things.

MR. HOLMES: And the reason for asking my question, I mean, this has been a position at least of NAMP for quite some time, is that, that even back as we were implementing or even prior to implementation of the pathogen reduction rule, is that, we had discussions over take out slaughter where we've got mandates for carcass-by-carcass inspection, but in the processing environment, processing plant environment, where the majority of the time, the inspector's not at the plant, you know, he covers three or four plants or whatever his circuit may be, we were told by the agency that until HACCP is implemented, we don't want to address that issue of working outside of your eight hours of inspection until HACCP is in place.

I know this is not necessarily directly related to that, but it does need to be addressed somewhere, hopefully in the near future, of running an

operation in a processing environment where I write what I'm going to do. I'm responsible for doing what I'm going to do whether you're there or not, and the fact that the majority of the time that I'm doing it, you're not there anyway, and when -- I guess the point is that a processing plant under the HACCP environment and HACCP inspection, in our opinion, should be able to work whatever hours they want to.

Obviously the agency needs to know what hours they're working. It's not just, hey, you can do whatever you want whenever you want. Tell us what you're going to do. I mean, that's -- it's not we don't want to do anything without you knowing it. It's we want to be able to run our business 24/7 if we want to, as long as we're generating the documents and doing the things that we're doing and we say we're going to do, whether you're there or not now anyway.

So, I just was curious about that. Thank you.

MS. SWACINA: Okay. Ms. Foreman?

MS. FOREMAN: Thank you.

This notion of a licensing fee, would you say just a little bit more about that, what you think it might involve?

MS. AXTELL: I'm hesitant to do so, only

because we're not ready to go into Phase 3, and we at this point are coming to that juncture last.

The description that I can give you, Carol, is what in our discussions with OMB folks we have been asked specifically to look at and that is more the notion of considering a basis upon which a license -- an annual licensing fee could be established and charged to all plants within the regulated industry.

There are a variety of ways in which one might consider such a licensing fee. We have not yet reached the point in the study where we have determined which particular path we might go down or which particular range of options we might look at as that part of the study. But the scope right now is something that could be considered to be done on an annual basis.

MS. FOREMAN: I don't know if it's too late to look at it, but for years, it has been clear to me that some plants, regardless of how many shifts they run, require greater resources from FSIS in order to meet their responsibility to the public under the law.

Those plants, for example, that have IDVs in there holding their hands day after day. That has been true forever, that some plants assume that USDA is going to be their quality assurance, their safety assurance.

It occurs to me that it might be useful to assess a certain amount or to establish that there's a certain amount of time that a plant should be able to get from FSIS free as part of its -- under the law, and that when a plant consistently requires additional resources from the agency because it is unable to, on a daily basis, meet the requirements that the agency's established, that there should be an additional fee charged there.

Those of you who need overtime are paying for overtime. Plants that aren't quite cutting it without somebody standing there holding their hand all day are getting that time free.

MS. AXTELL: Again, I can simply say at this stage, that OMB's view of what we should be examining in that part of the study was not risk-based but was more the notion of a straight licensing fee associated with the entitlement to be in business, in this particular business.

I understand that what you are suggesting is that one factor that we might consider as we approach that analysis would be a risk-based factor.

MS. FOREMAN: Well, it's actually -- it's more than a risk-based factor because I -- at -- I agree to a certain extent with Marty. If you had a

risk-based system, there's some of these plants that you might pass by and wave, and there's some of them that you'd want someone there all the time, plants that are now visited on a patrol basis. Just as a for example, Supreme Beef was visited on a patrol basis.

It seems to me that grinding beef is always a high-risk operation and that should have more inspection resources than the proverbial we're slicing the salami to put on the cheese pizza.

So, but even in a -- separate from the risk-based, there are some plants that are -- what was the word you just used, Sandy?

MS. ESKIN: Needs-based.

MS. FOREMAN: Yeah. Needs-based or that they're just having a problem. It's an operational problem rather than a risk-based, and those who aren't able to operate or that require additional resources in order to operate at an acceptable level ought to be charged a fee for that additional amount of resource that they're using. That would be fair to everybody in the industry. Yes, and it would be something of an incentive, I might suggest it to OMB myself.

MS. SWACINA: Question? Thank you, Carol.

Next, we have -- so, then --

MS. KASTER: My question may have been asked.

If it was, I apologize.

I know that you said that this was directed from OMB, this licensing fee, but do you know the thought process behind their directing you to examine that?

MS. AXTELL: Beyond what I've shared there, we haven't yet in follow-up discussions with them gotten into it any further than just the notion of a -- very similar to a business license.

MS. KASTER: I mean, is it driven because of the need for additional monies? Is it driven by making it more self-supporting? Do you know?

MS. AXTELL: Well, I think clearly, there's a realization that if we were to look at a different overtime rate structure, particularly one that might have a lower cost per hour, and we were to look to apply it differently, there is some thought that there would be a loss of revenue to the agency, and at some stage of the game, there's some question that that has to be considered in terms of whether the difference is made up from other appropriations, from the taxpayers or other means by which additional revenue is gained from the industry.

MS. KASTER: Results of Phase 2.

MS. AXTELL: Yes.

MS. KASTER: Okay.

MS. AXTELL: To a certain extent, that one -- some possible options that might be considered under Phase 2 might result in less revenue being available to the agency, therefore potential for some means to offset that. I would tell you that in the technical budget terms under which OMB is looking at this, they're not strictly -- even though they've asked us to look at this as a part of the budget process, it is not specifically being looked at as an offset to the appropriations or to the budget of the Department in the sense that this is being looked at, if you will, on the side.

In other words, it's not being used as an offset against budget caps that might be applied to the Department as a whole.

MS. SWACINA: Thank you.

Mr. Govro?

MR. GOVRO: Yes, thank you.

Carol's raised a good point, and I'd like to actually expand on that a little bit, and I don't know how constrained you are by the directive you have from OMB to look at this from strictly the standpoint of an overtime problem, but if it's a problem of equitable distribution of the costs of carrying out the program,

there are a number of ways that other agencies go about this.

Carol's touched on one of them. I would suggest that there may be other ways that you could assess fees. For instance, in state programs, retail inspection and so forth, agencies charge plan review fees for new firms that are going into business. They also charge for reinspection when conditions indicate that a follow-up is needed. Due to an -- and this really gets actually to the need provided by the firm, is that, they have proven that they need a follow-up inspection. That's kind of related to overtime in that you have to go back and do more work, and also resampling fees.

So, I think perhaps if you have the flexibility to look at the problem as a bigger problem, you might look at some of those areas.

MS. AXTELL: I think as we move to Phase 3 and we begin to look at that particular phase, I think there will be the opportunity to certainly introduce some other frameworks and determine if they would be acceptable within the scope that OMB is suggesting that we look at this particular piece of the puzzle.

Again, the origin of this is going back to this notion that the small and very small plants as a

group in aggregate may be disproportionately contributing to the overall revenue and that larger plants that are able to operate two full shifts aren't contributing.

Obviously as we're beginning to look at this, that basic assumption is one that we want to very carefully examine up front. We know that we have -- that of our large plants, most of them do in fact have two full shifts, but most of them are also contributing in total, in aggregate, probably about 50 percent in round numbers or slightly better of the overall revenue that the agency is receiving.

So, we are going to have to look very carefully at it and then again, we also acknowledge that, you know, there's a very healthy percentage of our small plants that do have two full shifts of operation right now that may well find themselves potentially in a position of having to pay significantly more to the agency along with the larger plants for the purposes of being able to maintain those operations.

So, there are some -- as we proceed down this, we want to make very sure that we have a good fundamental descriptive baseline of our current regulated industry and which sectors are contributing

which dollars to that revenue, so that, as we look at various alternative ways in which the rate structures could be examined, that we know what the intended and unintended effects may be and along the way, we would be happy, if the committee so desires, to continue to keep the committee updated on this particular matter.

I know that it is an issue that, as Marty has indicated, has come up in previous committee meetings in the past.

MS. SWACINA: Okay. Thanks.

Mr. Link?

MR. LINK: Maybe you answered this already and I just didn't get it, but on the licensing fee discussion, is that in lieu of overtime payment or in considering --

MS. AXTELL: No, this would not be in lieu of. It would be in addition to whatever the new overtime rate structure arrangement might be.

For example, if we did have a new overtime rate structure and it did involve second shift operations now being charged that overtime but we had a significantly lower hourly rate, and if in fact we are asked as part of Phase 2 of the study to then consider that as a 50/50 cost-sharing, there could well be a loss of revenue to the agency.

So, I mean, until we get all the numbers out and can draw this out, it's a little difficult to anticipate exactly what the effects would be, but to specifically answer your question, the licensing fee would be in addition to any other adjustment in the overtime rate structure.

MR. LINK: Well, I think -- I'm not advocating that we have to pay more money, but we've got plants that are single shift and we've got plants that are double shift, but in terms of equity, it might make sense that if there were a fee based on volume, based on number of inspectors, based on number of shifts you had, then you could equitably distribute that, I would think, without having to go through actually paying the overtime piece and everything else, I mean, just do in place of, but just a thought.

MS. AXTELL: Thank you. I appreciate it.

MS. SWACINA: Mr. Holmes?

MR. HOLMES: Charlie, I don't know if I heard you correctly, but I don't know that NAMP would be in favor of user fees if that's -- if this is another -- if we're talking about a licensing fee being another term for user fee, but that wasn't what I was going to say, but it just came to mind. I'm not sure that's what Charlie was agreeing to do.

MR. LINK: I didn't agree. I was just thinking --

MR. HOLMES: Okay. One thing and maybe it gets back to where Carol was coming from in terms of risk, but if a processing plant has two shifts, if you're looking at ways to free up resources and you've got an operation that's not a slaughter plant and you're not required to have an inspector there and under HACCP, you free up some inspection overtime or an inspector's time that may be a resource that could be used other places, depending on what the risk is, and so I don't -- there's a couple things that keep coming to mind, and that is, is that, I do think that risk should play a role in this cost-benefit analysis.

As to at least the report, the information that comes back should at least be able to identify what percentage of the plants or the dollars or both are in slaughter plants where you're required to have an inspector versus an establishment that may not require you to have an inspector in the plant every hour of operation. So, I just think that's some information that would be helpful not only to the agency but to the industry.

The other thing that comes to mind is when you talk about increasing dollars or the dollars to the

agency is when we start talking about dealing with negotiating with OJC regarding overtime and there are issues there. You're going to have some trouble as relates to dollars and what it means to the inspector when we start dealing with the bargaining unit and that kind of stuff, and I challenged Tom and Maggie both in that how -- depending on how these percentages break out between what -- how many dollars or what percentage of the dollars are going into the inspector's pocket versus the administrative costs, I really am concerned as to whether or not when you get to that bargaining table, if there's a significant amount of dollars going into cover administration fee, whether or not the agency will actually bargain and negotiate in a way that would remove overtime when it actually helps out the agency.

MS. AXTELL: Let me clarify one point up front. We do not negotiate salary rates for federal employees. Salary rates for federal employees, whether they are bargaining unit or non-bargaining unit, are set by various statutes and regulations.

There are places where there are statutes that give us some flexibility on the establishment of rates. A good example of that is the very recent passage of the Farm Bill and the provisions in the Farm

Bill that give the Secretary comparable authority under both the Meat Act and the Poultry Act to set the overtime rate of inspection personnel in those plants, but once that rate is set and the exercise of the Secretary's discretion is done, she also has under that authority the authority to establish the overtime rate.

There are other statutes that govern the fact that it must be full cost recovery. So, it's pretty structured in terms of the ranges there and even in the places where there is discretion that can be exercised by the Secretary, there are some limits on the amounts that can be set, but those are done outside of a negotiating process with a recognized unit.

MR. HOLMES: My concern is not so much what the rate is as to whether or not in a plant that's not legislatively mandated that an inspector be in it, that the agency might take some consideration on the process involved as to whether or not an inspector has to be in that plant and the plant be charged overtime for it. That's what I'm referring to more than what the rate is.

MS. AXTELL: Okay. Let me just clarify for the record, so we are on the same page here. Obviously, as you've mentioned before, that slaughter operations, because of the more structured manner in

which the regulations are presently written, the slaughter operations cannot be conducted outside of the presence of inspection personnel in the plant.

Processing operations may be, however, even in processing operations, there is the settled understanding that there will be at least one inspection visit per day which this agency has interpreted to be one inspection visit per shift and then during an overtime period associated with that shift, there is the -- the plant is still subject to an additional inspection visit proportional to the amount of time spent during base time at that processing plant.

So, even a processing operation is still fully subject to inspection and inspection visits during the course of a day. So, it is a different criterion but nonetheless still subject to inspection.

MR. HOLMES: Right. And I don't mean to beat a dead horse, but my thought is that if an inspector has a circuit and he's got four plants and he's got a 40-hour work week, and I know the statute probably doesn't allow him to do this at this point, but it's almost -- you could offer a flex time-type deal, kind of like you have these plants. This plant has two shifts. You decide, based on your schedule and working

with your circuit supervisor and the district or whatever, what is appropriate, but I just think there's an opportunity there to let plants that have the ability under HACCP to operate many times -- the majority of the time without the inspector in the plant, to operate longer hours and still continue doing what they're doing regardless without paying overtime.

I just think it's worth considering. I'm not saying it's easy, but we're not here to answer easy questions.

So, anyway.

MS. AXTELL: This is true.

MS. SWACINA: Thanks, Jeanne.

Okay. Next, we will have the Briefing on the Update on the National Advisory Committee for Microbiological Criteria for Foods and that will be given by Brenda Halbrook, and I believe everyone should have the handout of her presentation.

Briefing - Update on National Advisory  
Committee for Microbiological Criteria for Foods

MS. HALBROOK: Good afternoon, everyone.

I'd like to bring you up to date with some activities of the National Advisory Committee on Microbiological Criteria for Foods. We have been very active lately.

We held a plenary session in January, from

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January 22nd -- 23rd to the 25th, and during that time, we covered for topics: performance standards, blade tenderization and E.coli 0157:H7, hot-holding temperatures, and a Codex document, and then, finally, a new topic was introduced on criteria for shelf life based on safety.

I hope you have the documents, too, and I think under Tab 9 in your briefing books, that I will be covering during my presentation.

The Performance Standards Subcommittee on Meat and Poultry presented to the full committee for their review and vote a document that was produced prior to the subcommittee enduring the plenary session.

It was adopted by the full committee on January 25th, and the document which is in your books responds to Questions 1, 2 and 4 in full but Question 3 is a more quantitative question and it was not able to be resolved during this time period and the subcommittee's still working on it. It's a very -- very much a quantitative issue. So, it's taking more time.

These are the overall findings and general principles of the report. Performance standards can define the expected level of control in one or more steps in a process, and establishing and meeting performance standards can be a means of reaching public

health goals to reduce foodborne illness.

Furthermore, the stringency of a performance standard should be proportional to the risk and stated public health goals, and all of the general principles must be met. I should say that in Questions 1, 2 and 4, the report is broken out by general principles, current application and limitations, recommendations and data needs. So, everything falls into the same pattern.

The first question is: what are the key considerations when using risk assessments to develop performance standards? In order to assess risk, there are certain factors to consider, such as the concentration of the pathogen, pathogenicity of the microorganism, physical and chemical characteristics of the food, and the extent to which the food is processed.

In order to evaluate the current Salmonella performance standards, four points must be considered.

What was the level of risk of Salmonellosis prior to the performance standards for ground beef? What is the current risk for Salmonellosis from ground beef? What is the potential for new technologies to further reduce the prevalence of Salmonella? What is the risk of Salmonellosis if the performance standard is tightened?

Some of this can be handled by doing a risk assessment and everyone is interested in expedited risk assessments these days. So, one suggestion is that it can be expedited by doing -- making some changes to the existing FSIS risk assessment for E.coli 0157:H7 in ground beef, but they would need to substitute prevalence data and dose response data from the FAO/WHO Expert Consultation on Microbial Risk Assessment for Salmonella in order to make that expedited risk assessment.

These data, these are data needs now we're moving into, these data will help estimate the exposure for use in a risk assessment. Consumption frequency and serving size, methods of cooking, growth and inactivation kinetics, temperature and duration of storage through distribution, marketing and in the home.

Other data that are needed for this risk assessment would be to collect quantitative data on Salmonella in a HACCP verification program and also the recommendation is that these data be made available but appropriately codified for proprietary information, and furthermore, they would need to obtain epidemiological data on the proportion of Salmonellosis that is attributed to FSIS-regulated product.

We also need data on industry practices that account for lower concentrations of Salmonella, and we need to know how successful we have been in reducing other enteric pathogens with interventions that were aimed at Salmonella reduction. Those are all Question 1.

Question 2 is: what science is needed to support the use of an indicator organism in lieu of a specific pathogen, such as Salmonella, for measurement against a performance standard?

These are the factors that are required if you are to use an indicator organism. They must have similar survival and growth characteristics as the pathogen. They must have a shared common source for both organisms, such as animal intestines, and the environmental conditions that contribute to the presence of each organism must be the same, and finally, there is -- they did conclude that one pathogen can indicate the state or condition affecting another pathogen, if these previous criteria are met.

The committee also concluded that measurement of Salmonella reflects the total process control, particularly in microbial conditions of raw material in a HACCP system. So, in other words, Salmonella can serve as an indicator of total process control in a

HACCP system and it will particularly -- can particularly indicate the microbial condition of raw material in ground beef operations. This question that they're dealing with was specifically Salmonella in ground beef. So, it pertains to that.

Once again, there are data needs under Question Number 2. We need research to show whether a microorganism can be used to indicate the state or condition associated with contamination by a pathogen or pathogens of concern. We also need to know whether a microorganism can be used to show over time that reductions in an indicator lead to a reduction in the pathogen of concern in commercial operations.

But before we can arrive at numerical conclusions, we need to develop analytical methods and tools to determine whether there are any parallels between the reduction in these organisms is parallel between the organisms and the reduction in human foodborne illness.

Question Number 3. This is the question that has not yet been completely resolved. It has to do with regional and seasonal variations. Basically, it asks: what scientifically-appropriate methods should be used to incorporate regional and seasonal variations into performance standards?

The first conclusion of the committee was that acquiring and evaluating data on regionality and seasonality must be done using scientifically-appropriate methods. Where are those methods? What are the factors of concern surrounding them?

The committee recommends looking at all of the processes, from live animal to final product, including the microbiological status of animals presented for slaughter, slaughter practices aimed at contamination prevention, interventions to reduce contamination, and how the product is handled and held.

Other factors that must be considered are regionality, seasonality, husbandry practices, weather conditions, feed regimens, the age and health of the animals, conditions of transport to slaughter, and holding conditions prior to slaughter.

In addition, slaughter practices, such as these, might affect the microbiological status of a product and the sanitary dressing procedures that are used, hygienic standards of plant workers, the plant and its workers, line speeds, size and capacity of establishment and the equipment that is used.

These are the steps, the intervention steps to reduce microbial contamination which also must be taken into consideration. The washing of the product,

the use of organic acid rinses or antimicrobial compounds, and hot water or steam pasteurization, and how a product is handled and held can affect the product through these mechanisms of rapid chilling, temperature control, or recontamination. All of these factors can predict -- can affect a product's microbiological profile.

The current status of this question is that the subcommittee's still working on it. They plan to use HACCP verification data from the samples taken during calendar year 2001 in ground beef. They feel that this will give them a reasonable portrayal of national conditions for regional and seasonal variations, and they're working with a statistician to assess the likelihood of statistically-significant regional and seasonal variations for Salmonella using those same HACCP data that I just mentioned.

There are a few additional data needs for Question Number 3. Are the raw materials from a specific region or are they from a variety of regions? Is there raw material from multiple suppliers or is any raw material imported?

Question 4 is the last question on performance standards of the four that were presented to the committee last year in May. How can

quantitative baseline data best be developed and subsequently used in a quantitative performance standard is the gist of this question.

Again, general principles are stated regarding the usefulness of quantitative data as being more relevant to public health, important for exposure assessments in risk assessments. They are a way of measuring a reduction in pathogen concentration. They are a means of monitoring changes in concentration in relation to the time of year, but they present more technical challenges because the laboratory methods for quantification are more time-consuming and very resource-intensive.

In developing a baseline study, they advised us to consult a statistician, to design data acquisition procedures, make sure your number of samples is correct, and also consider items/issues, such as the source of the raw material, the date of slaughter, the date of sampling, and the type of establishment and production volume.

Secondly, for sample collection, shipment and laboratory analyses, which are critical, other issues would have to do with standardizing sampling methods, using accredited laboratories, and being sure that there is no growth or death of organisms during

transportation, and finally, determining the effect of processing on microbiological content of the sample.

Further considerations when developing a baseline study are to consider the shelf life of the product and to balance the information gained against the cost of acquiring the information. I might also add that since we're talking about quantitative data, qualitative data are less informative, but they do allow more samples to be taken because they are less expensive.

When developing quantitative performance standards, it is important to -- that the performance standards relate to public health consequences and demonstrate so that they can be -- the impact can be demonstrated and also bear in mind that they may be modified with changes in industry practices and also may be modified when new information on infectious dose becomes available.

Once again, we need research. We need cost-effectiveness quantitative methods for pathogens that are not as expensive as the currently-used most probable number technique. That wraps up the first four questions.

Then there were additional questions presented by Dr. Murano last Fall in her letter to the

committee, and in her letter, she asks these questions.

How well are performance standards working? Are they helping to ensure the safety of the nation's meat and poultry supply? Are there more effective alternatives?

If so, what would they be?

The subcommittee and full committee have not grappled with these yet. They have had them for quite some time but they have not come to that point until they finish Question 3 of the first original four questions.

The next steps will be to resolve Question Number 3 with the data analysis and then move on to Dr. Murano's questions and then on to ground products, other ground products, using this same format, for example ground turkey, and then after the ground products are completed, moving on to other classes and categories, such as carcasses. So, this question will be on-going for quite some time.

The second issue that we dealt with at our plenary session was blade tenderization and E.coli 0157:H7. There were originally four questions under this major question, and I will cover the first two questions, Questions 1 and 2, first, and then I'll move on to Questions 3 and 4 in less detail because there's less to say about it.

The first question is: is there any reason to conclude that translocation of E.coli 0157:H7 occurs with blade tenderization or similar processes that would render traditional cooking of non-intact beef products inadequate to kill the pathogen?

The second question is: do non-intact beef -- blade tenderized beef steaks present a greater risk to consumers from E.coli 0157:H7 compared to intact beef steaks if prepared similarly to intact beef steaks? I've highlighted the word "steaks" because the way the questions were posed, one had to do with steaks and one had to do with roasts, and the committee decided to split those two apart.

So, in the subcommittee meeting, there were two major sources of information that they had to review. One was a master's thesis entitled, "Escherichia E.coli 0157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steaks". It was done by Sporing in 1999.

The subcommittee also had a presentation by a Kansas State University representative entitled, "Evaluation of Pathogen Risks Associated with Blade Tenderized Beef Cooked to Varying Degrees of Doneness".

I might add that the full committee had the master's thesis to review, but they did not have the

benefit of the presentation. They had to listen to the summary notes from the subcommittee members.

This is what they found. There is some translocation of E.coli 0157:H7 during blade tenderization. There is the potential for an infected dose to reach the center of the cut with a single pass blade tenderization process. The greatest risk upon consumption is when the meat is cooked to less than a 120 degrees Fahrenheit internal temperature, and at 120 degrees Fahrenheit or less, the greatest risk is to those who are immunocompromised.

However, they also found that there is no greater risk to consumers than an intact steak when the steak is over-broiled or reaches an internal temperature of a 140 degrees Fahrenheit or higher.

Again, we have data needs. They did determine that the case control studies done by CDC did not ask the extent to which meat was cooked, whether it was rare, pink, well done or whatever, which led to a paucity of epidemiologic data in relating illness to these particular kinds of steaks, blade tenderized steaks.

Also, evidence shows that the steaks and roasts can transmit 0157:H7 but the investigational tools cannot discriminate between the commodity type

and the degree of pathogen transmission. So, we need better tools essentially in order to make those discriminating decisions and determinations.

Again, there is also a lack of industry data on the quantity of blade tenderized beef that's produced. We also don't know where it is distributed in retail, food service and so forth.

The final conclusion that the committee and subcommittee reached was regarding this Question Number 2, was that, the cooking instructions should be the same to consumers and the industry because the temperature is really the thing that counts the most, unless there is an alternative industry process that can be validated, I might add that.

Now, Questions 3 and 4 are: do blade tenderized roasts pose a greater risk? The committee found that there were insufficient data to answer this question. So, there just isn't an answer to this question.

Secondly, in Number 4, Question Number 4 is: do we have scientific data to support a labeling requirement for blade tenderized products? Once again, the conclusion of the committee was that there are insufficient data to answer this question as well. But a number of research needs came of this discussion.

For example, what is the survival of 0157:H7 in core samples of roasts after cooking to specified temperatures? We need to know that. What are industry practices regarding the types of blade tenderization equipment that are in use? How many passes are there through the tenderizer? What are the sanitation procedures for the equipment? What is the amount of product on throughput? What is the temperature of the processing room, and what is the temperature of the primal cut?

Those are all data needs that were identified as a consequence of this discussion, and I encourage you -- there are a few other data needs as well. I encourage you to consult your handout for the summary of this document and there's another longer list of research needs there.

Our third issue that was considered by the committee had to do with the hot-holding temperature guidelines in the FDA Food Code. The primary question was: should the hot-holding temperature in the Food Code be lowered from a 140 degrees Fahrenheit? If so, should there be monitoring and recordkeeping requirements? Also, is the margin of safety needed for a lower temperature? If so, what should it be?

The committee concluded that the temperature

can be lowered, but HACCP principles of monitoring and recordkeeping and documentation should be included in the Food Code for a period of 30 to 60 days.

In terms of a safety margin, there should be a five-degree safety margin above the growth range for *Clostridium perfringens*, and the caution is that hot-holding below a 130 degrees Fahrenheit might prove to be unsafe in food service and retail.

They also defined some time-temperature parameters. A 130 degrees Fahrenheit for a maximum of four hours, a 135 degrees Fahrenheit for a maximum of eight hours, or a 140 degrees Fahrenheit in definitely to which everyone said ooh, that would taste pretty awful after being held indefinitely.

When a 130 degrees Fahrenheit is not verifiable, they reached a further conclusion that the minimum temperature at the coldest part of the food at all times and the time and temperature should be increased if you cannot verify at a 130 degrees Fahrenheit. So, they put in the buffer and the safety margin there. That concludes the third topic.

The fourth is the Codex document that was brought before the committee. This is a draft paper, "Decision Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures".

The subcommittee as well as the full committee reviewed the document and made suggested changes and additional topics to be addressed. Those suggestions were incorporated in large measure by the Codex Committee on Food Hygiene. The document is currently under review at FDA, and it will be submitted at the next Codex meeting in January of 2003.

The new issue that was brought before the committee has to do with criteria for shelf life based on safety. This is our most recent subcommittee that was formed. They've been able to have only one meeting that was held April 2 to 4, and their basic question is: how do you establish safety-based use-by dates for ready-to-eat foods?

This subcommittee was formed as a consequence of the Listeria Action Plan which was produced in conjunction with the Listeria Risk Assessment, if you recall. It is a work-in-progress, and there's a greater amount of background information that's available on our NACMA web page.

As far as our future activities are concerned, we hope to have some subcommittee meetings between now and our August plenary session. I anticipate a meeting or so of the Performance Standards Subcommittee and of the Shelf Life Committee. I say

anticipate because it seems that everyone's summer schedule is so full of activities, it's proving very difficult to get them all together.

Our next plenary will be the last week of August, the week of August 26th, here in the Washington, D.C., area. I don't have any more detail than that at the moment. We have not settled on the number of days or the agenda, but all of that information on the meeting, where it is, the agenda topics and background information will be available for viewing on our website, and this is our web address where you can go and retrieve documents and get updates on meetings and any other kinds of questions you might have about the committee activities.

Thank you.

MS. SWACINA: Thank you, Brenda.

Questions? Comments? Ms. Donley?

MS. DONLEY: Thank you.

I have a couple questions. On your slide here, this Question 2, Salmonella as an indicator, was that quote taken from the Philadelphia report? Because I couldn't find it here in the paper that came -- that was distributed to us.

MS. HALBROOK: I took all the quotes directly from the paper that's in there. So, maybe we'll have

to put our heads together and try to find it.

MS. DONLEY: Dig for it. Okay.

MS. HALBROOK: Yeah. I'm sorry.

MS. DONLEY: Secondly, did I hear you say that Salmonella can be an indicator for 0157?

MS. HALBROOK: No.

MS. DONLEY: Did I mishear that? Okay. Good. Okay. And then, last, actually, when it talks about general principles in Question Number 1, I'm going to read this from -- directly from the page.

"This consideration of risk may not necessitate in all situations an in-depth quantitative risk assessment which requires extensive resources and time, particularly if it would necessarily delay timely protection of public health."

I guess I'm going to direct my question -- this question to Ms. Swacina, because I wrote in my margin here the Listeria rule, and my understanding, we've done one risk assessment already. There's another risk assessment being done. There is the -- I didn't mean to catch you by surprise there.

I just don't get it. This is a substantial public health threat. We've done one risk assessment. Why do we need another?

MS. SWACINA: I'm hoping Loren can help me

out here, speaking of catching someone by surprise.  
Judy can.

MS. RIGGINS: Let me say something about the Listeria. FDA and FSIS -- FDA had the lead on doing the risk ranking for Listeria and FSIS was a partner in that.

What that accomplished was to rank those categories of foods that we know will support the growth of Listeria. In order for us to do individual rulemaking, to establish performance standards for Listeria, we have to now do risk assessments that are pathogen and food category pairs to show that the -- I'm just saying that there's a next set of risk assessments that have to be done as a result of FDA's risk ranking.

That was simply to gather all the information that existed on Listeria at that time and to come out with a set of categories that we now know have to be further studied. So, we are aware that we have to, you know, for our -- at least for meat and poultry and egg products, we have to do a series of risk assessments that would show the relationship between times and temperatures and conditions of growth for Listeria and those specific types of products that we regulate.

MS. SWACINA: So, Judy, are you basically

saying that really all we did was a risk ranking based on the existing literature?

MS. RIGGINS: Yes.

MS. SWACINA: Existing data that existed at the time?

MS. RIGGINS: Yes.

MS. SWACINA: It wasn't really a risk assessment.

MS. RIGGINS: It wasn't a risk assessment that would allow us to use that information to do a rulemaking as such. We've got to do further work.

MS. SWACINA: Ms. Foreman?

MS. FOREMAN: I've got a couple of things. First of all, it seems to me that the advisory committee is saying specifically the opposite, that the consideration of risk may not necessitate in all situations an in-depth quantitative risk assessment which requires extensive resources, particularly if it would unnecessarily delay timely protection of public health.

I'd like to make a further comment here. We constantly hear from everybody, hold on, wait, wait for the Micro Committee, wait for the NAS, they're going to give us the ultimate answers. Well, the truth is they're not going to give us ultimate answers, and

they're not going to let FSIS off the hook. They are going to say as this one does, that pathogen reduction performance standards are scientific and are useful as an indicator of process control in ground beef and that it is not necessary to do a complete risk assessment if it's going to hold up public health protection. They are describing the risk involved and talking about some principles to pursue.

FSIS is a risk-management agency. You're supposed to base your decisions on science, but it is FSIS's responsibility to say this is an acceptable level of risk and these are the steps we're going to take to prevent that risk.

Having done that, this is an agency that's charged with protecting public health. You can either decide that you're not going to take one step until you have perfect information or you can do what I think public health agencies are supposed to do and that is, that it requires action to reduce risk factors based on the best available knowledge.

Now, we all know that there's lots more to be learned about pathogen control and microbial risk assessment and the possibility of health-based standards, and we need to pursue that. In the meantime, the agency -- it is irresponsible and

unacceptable for the agency to say that they're not going to take any action at all until that knowledge is forthcoming. We ought to act to reduce the risk based on what we know right now.

Second. Any proposed alternative or improvements in pathogen reduction ought to work at least as well as the ones that we've got now and work in a way that brings about continued progress in this.

Now, USDA has been bragging that Salmonella performance standards have reduced the prevalence of Salmonella and that is related to the reduction in foodborne illness.

MS. SWACINA: Actually, we've said HACCP has reduced.

MS. FOREMAN: You said the pathogen reduction and HACCP rule is the statement that was made and you -  
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MS. SWACINA: The entire rule, yes.

MS. FOREMAN: You can't separate -- I know the Department would like to play like Salmonella doesn't have anything to do with this, but I don't think that's viable.

You brag that this has been working. You ought to not stop doing what appears to be a reasonable part of a program that has had some success, and third,

the performance standards should establish a direct accountability for controlling those pathogens that are of the greatest public health concern and certainly Listeria because of its very high rate of hospitalization and in fact death ranks among those, but you can -- you know, all we've heard for two years now is we can't do anything till we got these final answers.

Well, this subcommittee, this committee has given you some answers and they say that having pathogen Salmonella performance standards in ground beef is a reasonable way to proceed, and I believe that it is the responsibility of a public health agency, since you've asked us here to advise you, it is the reasonable responsibility of a public health agency to act on the best available information that you have and not to take steps that will undo what little progress has been made in this regard.

Thank you.

MS. SWACINA: Thank you.

We do still have Salmonella performance standards. We do still have Salmonella performance standards.

MS. FOREMAN: Yes, I know, but they --

MS. SWACINA: We're testing every day.

Ms. Eskin?

MS. ESKIN: I just wanted to follow up.

Judy, I suppose, makes the most sense on the Listeria question. So, again, what you're saying is what was done by FDA in conjunction with FSIS was a Listeria risk ranking, and it's the FSIS's view that doing an in-depth quantitative risk assessment for Listeria is not going to be an undue delay in terms of protecting public health.

In other words, the agency believes that it is absolutely necessary to continue the risk assessment process before they go forward with any sort of rulemaking? Again, I'm just -- I want to understand if Listeria does or does not present in a situation that -  
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MS. RIGGINS: We are currently doing the work that we feel we need to in order to underpin the proposal for the ready-to-eat rule and that work is ongoing, and our Office of Public Health and Science is doing the risk assessment work that needs to be done to underpin that rule. So, we haven't stopped working. We've not, you know, abandoned it, but we know that there are requirements that we have to fulfill with respect to OMB and our Office of Risk Assessment and Cost-Benefit Analysis and so, we are doing that work in

order to satisfy the requirements that we are going to have to meet.

MS. ESKIN: And yet, you do put out a proposal that was before a risk assessment was done, is that right?

MS. RIGGINS: We put out a risk assessment based on the --

MS. ESKIN: A proposed rule?

MS. RIGGINS: We put out a proposal based on the best information that we had at that time.

Subsequent to that, a number of questions were raised.

FDA's risk ranking was completed because if you recall, we were -- we did our work before FDA completed the risk ranking.

MS. ESKIN: Right.

MS. RIGGINS: Once that risk ranking was done, there were questions raised. There were new -- there was new information presented that we now, in the face of that, have to work to answer in order to complete the rulemaking.

So, we have not stopped progress -- we've not stopped work on the rule, but we are aware of additional questions that we're going to have to answer and have a scientific basis for in order to complete the rule.

MS. ESKIN: Do you anticipate submitting -- issuing a repropose rule in light of this information that hopefully you'll receive or these questions? Is there any possibility --

MS. RIGGINS: No, I don't think that we're going to -- well, I think obviously it depends on the -- you know, how the risk assessment comes out, but we would anticipate hopefully going to a final rule once the risk assessment is completed.

MS. ESKIN: But the --

MS. RIGGINS: Now, there may be comments that we've received and therefore we cannot respond with a scientific basis, and we would have to repropose certain parts of it, but no, we intend to go forward with the final rule once the risk assessment work is completed.

MS. ESKIN: And is there any way you could give us any sort of sense of when that might be?

MS. RIGGINS: I don't know. Loren, do you have any sense of when the work that we're doing is going to be completed? Because it really does depend on that.

MS. ESKIN: I understand.

MR. LANGE: No, we don't have any real specific dates, but as a follow-up, a very specific

example, one of the areas that the OPHS Risk Assessment is working on relates to the proposed requirement of certain, you know, mandatory environmental testing for Listeria species.

The risk ranking or hazard ranking that some people refer to as done, doesn't help anyone answer the question that we think we'll need to support and that is, you know, show us that testing, environmental testing does indeed lead to reduced levels on product contact surfaces that then, yes, that leads to reduction in the product and therefore reductions in foodborne illness, and at this time, certainly we're responding to policy and trying to answer that question and still doing, you know, searches for data that could help answer that question, but we're sort of operating under the guidance that that question does need at least to be addressed better than it was in the proposal because, I mean, the proposal was sort of -- it was accepted on yes, Listeria's a serious problem, and you know, something should be done, and there was a proposal that the mandatory environmental testing, but we haven't been able to relate that testing to show that does that testing really give you a public health benefit and that's what we're struggling with.

MS. FOREMAN: And you believe you're going to

have to show that before you can put out a final rule?

MR. LANGE: We have that as an assignment in OPHS.

MS. FOREMAN: That is the most conservative interpretation of a public health protection I have ever heard of, and I think it's absolutely outrageous. Why don't you turn it around and say you're going to have the testing, unless you show there's not a relationship? That's just as reasonable a requirement to set forward.

Why not act to take the action, unless we know that there is not -- we know it's technologically feasible. Why not act to protect public health?

MS. SWACINA: I do want to add that we do test for *Listeria monocytogenes* already in cooked ready-to-eat product. We have zero tolerance for that. So, and that shouldn't be forgotten in this, but I do appreciate your comments.

MS. FOREMAN: I would like to go back and comment on your -- the agency keeps trying to have it both ways on Salmonella. Now, the Under Secretary told the National Meat Association that the Salmonella performance standard was not scientific and not accurate or reliable, and at the pathogen reduction --

MS. SWACINA: I don't think that -- I think

that's a misstatement of what she said.

MS. FOREMAN: I'm sorry. I don't have the document here, but --

MS. SWACINA: I don't either.

MS. FOREMAN: -- the phrase "not accurate and not reliable" were used in that speech.

MS. SWACINA: I think she may have said that it's possible that it wasn't accurate. It's possible that it's -- I'm sorry. What were the other words you used?

MS. FOREMAN: Not reliable.

MS. SWACINA: Possibly not reliable. I think her point was that it would do more damage. It would do more damage to have the performance standard that was -- I'm sorry. I'm really not thinking well at the moment. It would do more damage to have the performance standard that really wasn't based in science and would lead people to rely on the performance standard to their detriment. That's not what she said exactly either.

MS. FOREMAN: First of all, you say that, but then you say oh, yes, we're continuing to do this.

MS. SWACINA: We continue to test, right.

MS. FOREMAN: At the pathogen reduction conference, she said, I believe I'm correct, that the

0157:H7 was ridiculous, that it -- because one person got sick, because the young person at the Senate hearing got sick, it showed that it was a failure to have zero tolerance for E.coli 0157:H7, and that it was a failure, I mean, that it was a failure.

MS. SWACINA: She's saying that zero tolerance doesn't mean zero risk.

MS. FOREMAN: That's not what she said.

MS. SWACINA: That's exactly what she said.

MS. FOREMAN: That's not what she said.

MS. SWACINA: That's exactly what she said.

MS. FOREMAN: No, it is not. She said that it was a failure.

MS. SWACINA: I believe you on that. I don't remember her saying that.

MS. FOREMAN: Goes without saying that there's some of us who follow her comments very closely.

MS. SWACINA: I'm sure.

MS. FOREMAN: And the overall result is that the Department is sending the message that pathogen reduction, end product testing and pathogen reduction and zero tolerance for E.coli 0157:H7 is not something that the Department favors. The Micro Committee has said that pathogen reduction performance standards for

ground beef have some value, and they seem to look with some favor on them generally. They've said a complete risk assessment should not be pursued when that's going to get in the way of protecting public health.

We're just asking that the Department not turn around and stop doing some things that on Monday, you brag that it's helping, and on Tuesday, you say they're not accurate and not reliable and in fact are a failure when it comes to 0157:H7.

MS. SWACINA: There are no proposals on the table to end 0157 testing.

MS. FOREMAN: There are certainly comments made that the Department intends to move away from zero tolerance for 0157:H7. In her speech to the Food Marketing Institute -- actually, I'm sorry, not zero tolerance but mandatory testing, the Under Secretary indicated a preference for voluntary testing.

MS. SWACINA: For 0157?

MS. FOREMAN: Hm-hmm.

MS. SWACINA: Again, I do not know of any proposal. Are you aware of any proposal to stop the 0157 testing program?

MR. LANGE: No. The 0157 program is maintained at the current levels. The major change in the ready-to-eat testing programs was that the LM

testing was substantially increased, if you go back and look at the numbers, '95 and '96, to up through then 2000, late -- it was around 3,000. I think it's up over 8,000 samples a year, and the directive changed. It was 10 to 40.2, I think, that extended the micro testing to the full range of ready-to-eat products. So, -- and that increased the number of establishments where we were testing, and then there was a decision where we used to collect ready-to-eat sample and test it for either Salmonella or LM. All samples are now tested for both those, and if it's for minute sausage, it's also 0157 and staph enterotoxin, and if it's cooked ground beef patties, it's also 0157, and those programs are -- I mean, the amount of testing we're doing is constant or what was increased in the past.

MS. SWACINA: Okay. Dr. Morse?

DR. MORSE: Just had some questions and clarification on the summary on the E.coli 0157:H7 in blade tenderized non-intact beef.

I may have missed some of this, but it looked like from the slide presentation that at least in the laboratory, there was documentation that some translocation of E.coli 0157:H7, and then looking at that, there was actually an infectious dose, actually several times the infectious dose, because you need

only 10 organisms.

So, when you could carry the infectious dose into the center of this type of product, so there is a risk, that shows there is a risk, a greater risk than an intact piece of meat, but then I guess the Question 3, the committee showed there's a greater risk, at least the potential risk, and then they termed it was not -- they could not say there was a risk yet to the public, and I guess part of that, because the research needs, but at the bottom of that in the report, it says, "Additional data are being presented on January 24th, 2002, that would clarify that."

Were these questions addressed? Was there additional information presented?

MS. HALBROOK: Oh, that came from a study from, I think it was, the National Cattlemen's Beef had a meeting about the same time we had our meeting in January, and those data were not available to our committee for the consideration in our deliberations.

So, that is one of those things that's still out there. When we revisit this issue, if those data are indeed valuable and would change the conclusions, they will be incorporated, but it's my understanding that a risk assessment group took a look at those new data that were out in January, took a look at the data

that the subcommittee considered in NACMA, and they did a risk assessment using all of those data, and they all came out the same. They reached the same conclusion with the risk assessment that our subcommittee reached.

So, I think the bottom line is that the data that we didn't have on January 24th would not have changed the outcome of the conclusion of the committee, that the same conclusion was still reached.

DR. MORSE: I have a question for FSIS. Have you tested intact pieces of beef to see if there's been E.coli 0157:H7 on it?

MR. LANGE: No. We only test raw ground beef at this point for 0157.

DR. MORSE: I guess this gets back to the question of the wording, because the committee finds there is a potential risk. That means if there's -- if there was any E.coli 0157:H7 present on beef, then there is a risk because experimentally you've shown there's a risk, but there's been no testing to see --

MS. HALBROOK: Right. That's one of the data needs that we know we need further work, asking those specific questions, and since those data needs are presented in this document to the agency, the agency then can take those requests for new data and incorporate into our requirements for our research

agenda. So, that is a possible way for us to put those into our research agenda, get them out to our research partners and get some answers to exactly those questions, because we don't have those answers right now. We do know that there's a risk.

The cooking, I think, is the thing that takes care of the threshold of where the temperature -- they were really dealing with the temperature of the cooked product and what happens upon cooking, and so the risk then is at a certain temperature and below, then because --

DR. MORSE: I guess it's the same with hamburger. I mean, if you don't -- if you cook hamburger, you're safe, too, but if you have any presence of E.coli, you're at risk, and so here, the same -- why doesn't the same principle hold, I guess? It seems like, you know, you've shown in the laboratory, you can have an infectious dose in this product with this new technology. So, you're putting people at risk, and so, you know, the ground beef is made from beef which has the potential for E.coli contamination. So, it seems like there is a potential risk.

So, I mean, it seems like this is another question of delaying things. There is a risk posed,

but there isn't data to show/document that there's been illness, I guess, which is going to be very difficult epidemiologically.

MS. HALBROOK: Right. Yeah. The epi tools are just not that well developed, and they reach these conclusions using the little bit that they have. We also have a lack of industry data. We don't know how much of these products are being produced and where they're being sold and who's consuming them. We just don't know. So, there's a lot of other information, that if you were to do a risk assessment, for example, those kinds of bits of information would have to be assumed. We don't have those data, those hard data to incorporate, but even without that, we were able to reach the same conclusions with a risk assessment, that there is a risk. It can be ameliorated by a cooking procedure to a certain temperature and then the knowledge is that there is still a risk if those products are cooked -- are not cooked to above a 140 degrees.

MS. FOREMAN: May I follow up on that? kay.

DR. MORSE: One follow-up. It seems like then that we should recommend that FSIS test and look for E.coli 0157:H7, if no one is doing that, because if we find it, you test a number of products like you're

testing hamburger and you find it, then that should seal the case. There's no question then. If you have it, then at least the patient -- consumer population should be warned because then you'll document that it can be on. You've got an adulterant that can be on this, and with this procedure, you're increasing the risk, and then you have an obligation to warn the public.

So, it seems like there's an obligation on FSIS to start testing to see what the extent of the risk is.

MS. FOREMAN: May I follow up? I think, is there a difference between ground beef and blade tenderized beef in the eyes of the Micro Committee because they believe there's not a risk of cross-contamination with the blade tenderized? Because certainly USDA has argued that there's a zero tolerance both because it's an -- this in this case is an adulterant, but the -- I -- the only thing I can figure is they must think there's some difference because they think it's not present on the outside of the product.

So, otherwise, because if it is, cooking's not the answer because then you have cross-contamination potential. It's on the outside, you got cross-contamination.

MS. HALBROOK: Right. And I think -- well, as I stated in the beginning of that section on blade tenderization, the data that we have to work with had to do with one pass of a blade. We don't have information on industry practices, how many passes they put through the blades, how many -- what the throughput is of the amount of product going by, what the sanitation procedures are.

So, I think in terms of the questions on cross-contamination, we have a lot more questions than we have answers.

MS. FOREMAN: Well, it does strike me, though, that I remember some of these questions from the beginning, and it was clear that there were at least three or four passthroughs ordinarily in blade tenderization. So that, you know, you could have just said the data you have are garbage because nobody does a one pass with blade tenderization, and the data, I believe, also showed that, of course, each subsequent cut through brought the potential for additional contamination.

MS. HALBROOK: I think that's where the major research area still lies.

MS. FOREMAN: So, we're not going to do anything till we have dead bodies.

MS. HALBROOK: Well, again, the epidemiologic data that we have really don't help us any at the moment. We need to improve those tools as well, so we have a good complement of research in the laboratory and epi data in the field.

MS. SWACINA: Mr. Holmes?

MR. HOLMES: Kinda following up a little bit on what Carol's talking about and even Dr. Morse.

The research that KSU did, they took -- I may not be exactly right here, but they actually grossly contaminated the exterior surface of those primals, and I believe it was six logs that they actually put on the surface which is certainly considered gross contamination and not what you would typically find anywhere after a carcass runs through all the different interventions that are being done.

Then when you take into consideration that that carcass is further cut down into subprimal and further a subprimal and maybe even trimmed prior to going through a blade tenderization, and I agree with you, two passes is probably the minimum that somebody is sending that product through.

So, I'd say at least two passes, but when you take into consideration that research was done on a six log and we're not even seeing that in industry and then

you're further going into an interior muscle, further trimming it before it ever goes through, you're also not comparing apples to apples in that regard either.

So, they took the worst case scenario, at least on the contamination, and even worse than a worst case scenario on the contamination on the surface, but you're right, it should have been done with two passes.

If I'm not mistaken, this was Randy Fevus and Dr. Jim Marsden, and I believe they've gone back to do further research on multiple passes, and I don't know all the details from that.

But anyway, back when Michael Taylor and the agency considered 0157:H7 an adulterant, their position was that it was an adulterant in ground beef, and the reason for that, if I recall correctly and somebody help me, correct me if I'm wrong, is the fact that at that time, the consumer's cooking methods on ground beef patties was not what it is today, and because people were many times eating non-fully-cooked ground beef patties, there was a difference in the risk between eating a medium rare hamburger versus a medium rare steak, and the reason for that was because of the grinding process of moving the 0157:H7 to the interior of the muscle.

Now, obviously blade tenderization has shown

that it can do that, too. However, because of the time and temperature relationship between cooking a thicker steak versus hamburger, you -- the research was showing that there was no differentiation, I believe, up to a medium rare temperature on the steak, that there was no difference in risk to the consuming public and that's my brief understanding of the whole thing and that may go to some of your questions there, Dr. Morse, too, in addition to the fact that at least to this point, roasts and steaks have not been associated with someone that has had 0157:H7.

MS. FOREMAN: Is it the Department's position that E.coli 0157:H7 is still an adulterant in ground beef?

MS. SWACINA: Yes.

MS. FOREMAN: Thanks.

MS. SWACINA: In raw ground beef.

MS. FOREMAN: Raw ground beef. Yes, thank you. That's very important.

MR. HOLMES: Well, would be in cooked ground beef, too.

MS. SWACINA: Certainly. Mr. Holmes, did you have anything else?

MR. HOLMES: I'm sorry. Excuse me.

MS. SWACINA: Okay. I don't know about

anyone else, but I need to take a break. So, if we could come back in 10 minutes? If we can come back in 10 minutes, then hopefully we can get through everything.

Thanks.

(Whereupon, a recess was taken.)

MS. SWACINA: The next presentation is on Biosecurity, and it will be given by Jesse Majkowski, who is one of our representatives on that issue.

Briefing - Biosecurity Update

MR. MAJKOWSKI: I told the guy that was operating the slides that we'd have a 10-minute break, and I guess he decided to take a little bit longer. Is he back there?

MS. SWACINA: There was somebody back there, yeah.

MR. MAJKOWSKI: Thanks. Thanks a lot.

Well, good afternoon. I understand it's been, how shall I say, an interesting discussion the last two days, and I had a number of things in my notes that I've cut out, like any mention to standards or pathogens, 0157, you know, just try to make it interesting. Okay.

What I'm going to try to do is cut this down a little bit because I know it's been a long day, the

weather's getting bad out there and everything, but what I'd like to do today is talk to you a little bit about what we're doing in the area of biosecurity.

One of the reasons that we're here is that the agency has embarked on some efforts on biosecurity, and we got started in October-November, and we've got some things going, and we think it's about time now that we got this information to the advisory -- our advisory committees to have them give us some input and comment and raise some questions with us.

Most of you know what our mission and role is, and this is the type of presentation that we're generally doing when we go out to talk with industry groups, consumers and other public entities.

One of the things I wanted to explain was there was a lot of confusion about how we're organized with biosecurity. Who's in charge? Well, it starts at the top, at the White House. Homeland Security headed by Governor Ridge's office is the office that's really responsible for coordinating all the efforts within the Federal Government.

Within USDA, shortly after 9/11 and some time in October, we formed a Homeland Security Council for USDA. This is at the Secretary's level and Under Secretary's level. There's three subcouncils advising

the Secretary. One of these is on the protection of the food supply and agricultural production. The Food Emergency Response, Rapid Response Evaluation Team is part of that, and our Under Secretary and the other Under Secretaries involved with food are in that subcouncil.

The other two have to deal with employee safety, structures of the buildings, the facilities that we have around the country.

Within FSIS, we have the Food Biosecurity Action Team. That is a team that we formed, myself and Carol Seymour are running that team, to try to coordinate all the efforts in the agency that have to do with emergency responses biosecurity. So, that's within FSIS itself.

Outside of the agency, we have the PrepNet Group, Food Threat Preparedness Network, and that's composed of agencies that are within USDA as well as outside. It's chaired by our Administrator of FSIS and the Administrator for SHFSAN. We have FDA, CDC, and DoD involved in that, also.

Just to reiterate, the subcouncil, FERRET has come under that, and FERRET is really a part of that subcouncil. If you have some questions on the slide, just raise your hand and stop me because I'm going to

try to go through some of these quickly. Some, I'm going to spend a little more time on.

PrepNet. There's been some confusion. Well, what does PrepNet do with all these other activities? Well, within USDA, of course, we have our coordination with FERRET with all the agencies. PrepNet goes outside the agencies. SHFSAN, CDC, EPA, DoD, all are working on emergency response, laboratory capabilities, and we're all aimed at prevention and deterrence. Many of them are developing documents. We're developing documents. We're looking at how we can share that information, have some commonalities.

The other good thing that this does for us, should there be some event with the food supply, we have contacts in all these agencies at high levels that we can get staff and other people working together to try to tackle that situation.

Well, what is F-BAT's mission? Our responsibility basically is to coordinate and facilitate the activities pertaining to biosecurity. What we're trying to do is to coordinate the efforts within the agency. Most of you know our agency pretty well. We have an Office of Public Health and Science. We have risk assessors in that group. We have our recall function in that group. We have field

operations. We have compliance, district enforcement.

All of them have some part of this independently. Our job is to try to pull that all together.

We have basically five goals that we've been working on since November. One is to ensure the continuation of FSIS essential functions during emergencies. We have set up plans for our offices to operate outside of Washington should some event occur.

This was really spurred by the Y2K event coming about. We put plans together to move our decisionmaking capability outside of Washington, D.C.

If you think of what happened at 9/11, Washington, D.C., shut down. All of us went home. Many of the decisionmakers were gone. Meat and poultry inspection went on without a blip. Products were flowing. The plan worked relatively well.

We want to ensure our employees safety pertaining to terrorism, bioterrorism, and emergencies.

Shortly after 9/11, we had a number of anthrax hoaxes or threats in numerous plants. We pulled our inspectors out. We waited for local hazmat, local FBI to come in, and other local law enforcement to give us an assessment of what the situation was before we allowed the plant or products to be shipped out of that plant.

We're also trying to ensure that we're prepared to prevent and respond to any acts against the food supply, and I'll go into a little more of that detail later.

We want to ensure proper communications with the industry, consumers and within FSIS. We've put out a backgrounder that's on our website already on biosecurity. Most of the information that I'm talking about today is on -- in that backgrounder.

One of the important things about the communications, I'll just give you two examples, is that a month or two ago, we had a report of an animal in Kansas that had blisters on its mouth. That report got out. Not too much further information came out. The meat markets, the beef markets and whatnot suffered dramatic effects based on that report.

A couple of years ago, we had an outbreak in Texas, and they indicated that it was strawberries from California. The market for strawberries was ruined in California when it was actually another item. The importance of the communications and how we communicate an event to the public is going to be extremely important.

We have a communications group within the agency that's working on this. We're trying to put

together some sort of boilerplate language that we would use should something occur as well as we have people at the Department level that are working on this.

Also, we want to ensure the security of our labs and have adequate capacity. Again, with the anthrax scares and threats and hoaxes that were going on, we had one of our labs that opened a box, some powdered material came out of that box in the area where they were receiving samples. We lost all those samples. We had to shut down that lab for several days until we determined whether it was safe for our people to go back into there. Results of the analysis were held up. We needed to make plans on how to handle that situation, and we've been working on that.

Well, what have we been doing in terms of improving our ability to prevent threats to the food supply, early detection and ensure containment? We have been working on a vulnerability assessment of the food supply from the farm to the table, and we're looking at this in a very detailed fashion. We're looking at, for example, if someone introduces a BT agent at a certain point in the processing, how many people would that make then become ill? How much of that agent must be introduced?

We're just about near completion of that assessment. Once that's done, the question that it raises for us, how are we going to get that information out? How can we make it available? It really boils down to really a recipe for disaster if someone should get ahold of this document. So, we have a lot of concerns about releasing that information, but yet when we see these vulnerable points, we need to be able to do something about them.

We are going to be taking a next step, once that's completed, looking at what can we do or what is in place today that prevents that agent from getting through the food supply? Needless to say, one of the areas that was identified obviously is ready-to-eat products. I don't think that's any secret to anyone. Transportation is another area that's been identified, also.

When you think of any of the liquid products that are being shipped around the country, sweeteners, syrups, liquid eggs in tanker trucks that are unsealed at truck stops. Many meat and poultry products are sitting on trucks at truck stops unattended, unlocked.

The other area that we're working on is a prevention and response plan. A number of people have asked, will you respond to emergencies on a day-to-day

basis? Why are you doing -- what are you doing here? What we plan to do is we're working right now on issuing a notice on the development of an emergency response team within the agency, and this team is going -- we want to formalize this emergency response team, and we're going to develop a standard operating procedure for this team.

They're going to be really just dealing with deliberate acts of contamination, and some people have said, well, how's that any different how you deal with contamination today or deliberate act? Well, we'll be looking at -- this team will be looking at not only the situation that happens and controlling that like we normally do but does that go beyond that plant? If it was the feed that was used in poultry, was it only that one particular plant? Was it a corporation? Is it spread throughout the country? Should we be doing other testing? Should we be getting FDA involved?

These types of questions normally don't get answered when we handle a normal contamination issue, such as some foreign material in, let's say, ham products which we had a recall on several months ago. But these are the types of questions this team will be looking at and working with some of the other agencies.

Strengthening our laboratory systems security

and the capabilities. We've been working on that. Enhancing the internal/external communications. One of the things that we put out and we had these on the back table, I don't know if they pulled them off, it's the Guidelines for Food Processors. It's one of the few times, I think, that we've put out something in color in a booklet that looks kind of slick.

The other area that we really started much before 9/11 was the consumer complaint system. We had -- some people were looking at our computer -- I mean, our consumer complaint system and one of the things that we found out, that we didn't have a centralized database. Well, we've centralized that now. We now have a database where we can begin to look at consumer complaints that come into the agency, whether they come into the plant, get into Washington, whether they come in the field. This is going to help us immensely to pick up anything that's happening out there in terms of deliberate acts against the food supply.

Some of the other things that I'd like to mention, after 9/11, we placed all our inspectors on a heightened alert, and people have asked, well, what did that do? We've had numerous reports from inspectors and plants of threats to public officials in Washington, to people threatening the food supply, to

sabotage acts against companies. All this information was turned over to our Office of Inspector General, the OIG Office, who then, with the FBI, investigated those situations.

We're still getting that information in today. There's still a sense of heightened alert out there by our inspectors, and if you think of this, we have 7,600 inspectors out there in plants, 200+ compliance officers throughout the country. They're really our eyes and ears for detecting that something's going on and perhaps can give us an early warning.

Our veterinary medical officer positions in the district office are going to serve as an information source and a response team for bioterrorism. One of the things that we're finding is we're getting a lot of requests from industry groups, state groups, local groups, to talk about what is the agency doing for the meat and poultry supply? How are we protecting that against any bioterrorism acts?

We're going to be training them on doing this presentation and probably a two-day workshop some time this summer. So, they will be sort of our voices out there in the field for the agency.

We're also strengthening our coordination and cooperating with law enforcement agencies. One of the

things that we are lacking in agriculture, at least, is any intelligence on threats to the agribusiness per se.

We've never had to do that before ourselves, FDA. We just recently met with the IG's Office and they are going to take the lead on pulling the other agencies within USDA together to begin to look at what are the needs of the various agencies for intelligence.

Right now, intelligence is being gathered, people are analyzing it, and, for example, the State Department would go to the CIA or FBI. These are the things we're looking for. They would comb through their reports and look for this. They don't have that for agriculture. That's what we're going to be working on to do.

In terms of training, the Department's received a sizeable amount of money for biosecurity, bioterrorism. Some of that money was given out in terms of grants. A portion of it came to the agency. We're using a lot of that money to strengthen our cyber security, the physical structures, like the laboratories. A good portion of it is going to training our field force. We are in the midst of developing plans. We expect to start training people some time this summer.

The continuation of our operation plans, too.

I mean, this really paid off in the event of 9/11. These are working. We're continually looking at them and trying to improve them, testing out our emergency numbers.

Finally, one of the last things that we have done is we needed to take a look at our website and remove a lot of the information that was on that site in terms of what someone could use or use against us. Some of that information is available, other through printed form and some of it is not, but we've gone through there and taken a lot of that information off.

So, I think in terms of biosecurity, of what the agency is doing, is we are attempting to try to coordinate some of our normal emergency response systems and pull them under one umbrella, and what we're looking at is should some of event occur, having a group of people in place that will be able to deal with that and look beyond the situation that happens at hand.

For example, any deliberate contamination of a plant, we're going to deal with that situation. The product will be recalled. The company'll pull product back and so forth. But we'll be looking much more beyond that.

So, with that, I'll open it up to questions.

MS. SWACINA: Yes, Dale?

MR. MAJKOWSKI: They must want to go home.

DR. MORSE: Just a quick question. Are there really enough veterinarians to cover? It's great you're going to have these new district veterinarians, but a number of states are also hiring, you know, veterinarians, and we're finding the same thing with epidemiologists. There are not enough people. So, are there enough veterinarians that are trained to -- coming out potentially to recruit people?

MR. MAJKOWSKI: Well, we have 17 positions. Those are -- well, 15 now, I guess. There -- 17. They're all filled. So, we're able to fill those positions.

DR. MORSE: Great. Good. That's why we're going to have a hard time.

MR. MAJKOWSKI: Right. We beat you to the punch.

DR. MORSE: Yes. Okay.

MS. SWACINA: Dr. Johnson?

DR. JOHNSON: Consumer complaint monitoring system.

MR. MAJKOWSKI: Yes.

DR. JOHNSON: It sounds really good. Could you explain a little bit more about what you're doing,

and are you communicating any of this in generic terms to industry, that they might be more alert to certain situations?

MR. MAJKOWSKI: Well, we are sending back to the plants, when we get a consumer complaint about that specific plant, and we're looking into see what trends there are, and we haven't seen any at this point in time.

We've -- prior to this, all we had were pieces of paper and those pieces of paper flowed between different parts of the agency and back to the field and back -- and phone calls were made to plants.

We now have a database where we can do searches and do some analytical work to see that, you know, last week, we got five complaints about cooked poultry, and it had XYZ in it, you know. Is there something going on? It looks like it's from four different companies. That's the type of thing that we're going to be looking for when we analyze that.

DR. JOHNSON: And you would share that information with industry in generic terms without using company names?

MR. MAJKOWSKI: Yes, more than likely, we would.

There's another structure that's been set up,

too. If I can find my notes here. Yeah. I'm not sure if everyone is aware of this, but within the FBI, there is a National Information Protection Center, and they receive reports or threats against the food supply. They have set up approximately eight information-sharing advisory councils. One of these, I think FMI, has headed up and is the one for food, and when threats come in, they'll go to this National Information Protection Center and they will assess that threat and they will contact the appropriate ISAC.

The interesting thing is that they now have gotten security clearances for some of the people in these ISACs. So, if we get some secure information, that will be able to be shared with some of those individuals who -- and then we'll have to sort of cleanse it to get it out to the appropriate people. So, there are mechanisms in place to share that.

We're really with the consumer complaint system in the infancy stage, we've just got it up and running, collecting data. We haven't started to really analyze it yet per se.

DR. JOHNSON: But you do envision coordinating through the ISAC, the Food ISAC --

MR. MAJKOWSKI: Yes, we're going to have --

DR. JOHNSON: -- if there was an issue?

MR. MAJKOWSKI: We're going to have to do that. It's the most logical place to coordinate the information.

MS. SWACINA: Ms. Eskin?

MS. ESKIN: I have another question on the consumer complaint issue.

MR. MAJKOWSKI: Yes.

MS. ESKIN: Obviously as part of your increased surveillance, looking for intentional contamination, you may come across unintentional --

MR. MAJKOWSKI: Right.

MS. ESKIN: -- food contamination and again you're having a database with these complaints.

Is there any thought to sharing this information where appropriate in an appropriate form with CDC or relevant state health departments? In other words, this may be information that they're not going to otherwise get.

MR. MAJKOWSKI: Well, generally, with consumer complaints, when we -- many times, they're just an isolated incident or something that we can't really validate. The best example I can give you is that we had a complaint one week of some pieces of plastic in ground chicken.

MS. ESKIN: Hm-hmm.

MR. MAJKOWSKI: Thought it was an isolated incident, you know, and got the product, tested it and found some very small pieces, nothing else. Next week, we got another complaint, same company, same plant, different date of production.

MS. ESKIN: Hm-hmm.

MR. MAJKOWSKI: We then went out and began testing product and so forth, eventually did a recall on that product.

If there were illnesses involved with that, we would be getting CDC involved.

MS. ESKIN: Okay. That's --

MR. MAJKOWSKI: Okay.

MS. ESKIN: -- just what I wanted to know.

MR. MAJKOWSKI: Yeah. Okay.

MS. ESKIN: It hasn't happened obviously, but there's --

MR. MAJKOWSKI: No, it hasn't happened.

MS. ESKIN: -- always the possibility.

MR. MAJKOWSKI: It hasn't happened, and many times, we -- the reports that we get, you know, I ate Alice Johnson's product and I got sick immediately, you know, and, well, did you go to the doctor? No, but I'm still sick, and so we don't have any documentation for us to act on.

MR. GOVRO: I participated in an exercise at a conference that was held by FDA up in the Bellingham area a few months ago. There was some USDA personnel there, local personnel. It was a conference that consisted of Oregon, Washington, Idaho, Alaska, Montana, USDA, FDA, and we did a tabletop exercise where information -- we were given information a little bit at a time as if it would have developed from a foodborne illness that maybe turned into an event.

MR. MAJKOWSKI: Right.

MR. GOVRO: And it really taught us a lot about how unprepared we were to respond to an event when multiple agencies would be involved, and then the wild card, of course, is what happens when the FBI comes in and takes over and has different concerns about keeping information secret because it's a criminal investigation rather than going public with it to protect public health, and I would just recommend to perhaps the Office of Homeland Security through you that more exercises involving the actual players and beyond -- well, it would still have to be kind of a tabletop exercise, but to go through that. I think it would be very instructive and beneficial to everybody.

MR. MAJKOWSKI: Just to give you -- not to steal your thunder, but --

MR. GOVRO: No. Go ahead.

MR. MAJKOWSKI: -- in our training package, we have planned for tabletop exercises. What we want to do is we want to do one with headquarters people here in Washington and people said, well, we know how to handle emergencies and so forth, and I keep saying you'll be surprised at what we don't know and what we don't do.

It's interesting. I participated in one at FDA, and we had AFIS there and Marcells and it was a BSE tabletop exercise, and it had to do with feed. The interesting thing was that FDA couldn't decide whose responsibility it was to call the foreign country where the feed came in. Everyone thought it was your responsibility. They thought it was AFIS's. AFIS thought it was this, and it was very interesting, the questions that it raised. So, it's very valuable.

What we intend to do once we do that, raise those issues that we don't have answers for and get answers and take it down to the district level, to the field level, and really see if it works or not and that should give us some good feedback. So, we're hoping to be able to do that, start doing that this summer. But you're right.

Thank you.

MS. BAYSE: Your slide on FSIS biosecurity actions, if I understood you correctly, under assessing vulnerabilities --

MR. MAJKOWSKI: Yes.

MS. BAYSE: -- in the meat and poultry and egg products supply, you indicated you were just about -- that was just about complete.

MR. MAJKOWSKI: Hm-hmm.

MS. BAYSE: That sounds to me like an extraordinarily difficult thing to complete. So, could you give us some idea? You've done worst case scenarios.

MR. MAJKOWSKI: Well, I mean, to give you an example, what we did is we took a look at the food supply. We took a look at the BT agents that CDC mentioned, DoD mentioned. These were all websites and they're pretty well known.

We took a look then -- we had our risk assessors really doing this. They took a look at how easy was it for someone to come in to get this and how easy it was for someone to make this, and then they came up with a formula basically, and I'm not the best to explain it, but they took that as a factor, the ease of making it, the ease of introduction, and then the type of product it would be introduced into and the

number of people that it could possibly make ill to take a look at what was the risk of that happening.

Good example is arsenic. Okay. Arsenic gets introduced into the food supply or into feed, and are we going to have animals coming through slaughter? Well, more than likely not. Those animals will probably die and never make it to slaughter.

What this document does for us is really gives us a good base when we get a threat that someone said we put XYZ in so and so's product, and it was this finished product. We'll have assigned space to take a look at that to see whether is this really a hoax? Do we need to react to this? How much concern should we have on this? So, it's a pretty detailed document, and it took a look at basically, I guess, how much did you need to contaminate a 2,000 pound bin in order to get X number of people ill?

MS. BAYSE: You'd have to look at the level of toxicity because XYZ can range from parts per trillion to parts per thousand.

MR. MAJKOWSKI: Well, what we were looking at is how much of the agent had to be introduced into that bin to make 10,000 people ill, and, you know, suffice it to say some agents, you only needed 35 grams. Others, you needed 35 or 40 pounds. Okay.

MR. HOLMES: Jesse, I appreciate the presentation. I find it interesting. Carol's not here to hear this, but I was just curious. When you're talking about what Gladys was bringing up and maybe you can allude to it a little bit because you talked about a 2,000 pound bin and so forth, but we were talking earlier about small plants and large plants and security measures and guidelines and so forth.

Was there any discussion versus where there was some vulnerabilities in small plants versus large plants or was it really just in relation to amount of product to affect --

MR. MAJKOWSKI: It was basically just looking at the food supply from farm to table, not taking into consideration plant size or anything of that nature. That was the only thing that we looked at, and we haven't gotten to the point of saying, you know, you have a small plant operator here that only produces a hundred pounds a week. Should we really be concerned with that because that's only going to mount in X number of people and so forth versus this plant down the road that produces a 100,000 pounds every week and that's distributed across the nation? We didn't get to that at this point.

MR. HOLMES: Thank you.

MS. SWACINA: Okay. Okay. I keep forgetting. Loren Lange had a response to Nancy's question about labs, and we were going to give a lab update. I guess at least we can go ahead and put it on the record.

MR. LANGE: Okay. The question, as I understood it, is, what is the process for validating new laboratory methods in FSIS? I'll try to give a brief summary, and I will sort of stick to micro methods because they seem to be of more interest today than some of the chemical residue methods.

Just real briefly, FSIS has three field labs in Athens, Georgia, St. Louis, and Alameda, California. It also has a fourth lab for micro which we call -- I always have to read it. It's FSIS Microbial Outbreaks and Special Projects Branch Laboratory in Athens, Georgia. M-O-S-P-B Labs. That exists in Athens, Georgia.

Now, all four of these labs in the last year have received ISO certification. This MOSPB, what we call the MOSPB Lab, has a continuous process of talking to ARS, reviewing scientific literature, consulting with other agencies and stuff. So, they're always sort of looking for any laboratory procedure that might reduce the time to test a meat and poultry product that

would give, let's say, false -- reduce false-positives on a screen test, get results back to plants more rapidly. So, it's an on-going review that they do and they're charged with.

If they think there's something useful, they actually bring it into the MOSPB Lab and evaluate it there and see if they can get it to work. If they think they have something that works, then they get together with Assistant Deputy Administrator for our laboratories, which is Patrick McCaskey, and there's a plan developed for evaluation of a process in the field lab side-by-side with the existing method, and things like laboratory personnel training, how many samples and how rigorous this should be, sort of all defined by documents that were developed to proceed with the ISO certification.

We have to have standardized procedures. We have to have procedures to evaluate new things that meet sort of the criteria to get the ISO certification.

So, in the end, after MOSPB decides it's something that's worth evaluating, it gets evaluated in the field lab. There's a final report and recommendation is made within the agency to adopt it and it would be sort of announced through Public Affairs and eventually put on the website.

An example just recently was, there was a press release on April 30th that was announcing the implementation of what was the BAX Method which was a screen for LM in meat and poultry products. It reduced the time to report negatives back to establishments by one day, and it reduced the false-positives.

The process of getting that from when the MOSPB Lab first started trying to evaluate that to getting the final approval was about six months. So, it's a fairly rigorous process and includes testing alongside the existing method and certainly ends with public notification and putting the process on the website.

MS. SWACINA: Thank you.

Any questions?

(No response)

MS. SWACINA: Okay. I'm going to turn it over to Charlie to discuss the Remaining Issues and Plans for the Next Meeting.

Remaining Issues and Plans for Next Meeting

MR. GIOGLIO: Okay. Thanks, Linda.

I actually have two quick things. One, I want to circle back actually to the committee's meeting October 31st, I believe, October 31st, November 1 of 2000. We discussed an issue regarding recall

distribution data and sharing those with state programs and other federal agencies and so forth.

I think at that time, I had presented that issue and had gotten some very good advice from this committee. I really just wanted to report out that we took your advice. We did at that time propose a rule, got public comment, so forth, and went back, revised the rule based on the public comment. We have gone final with that rule which is planned to be implemented, ready for implementation, I guess, July 31. We should go live.

We're right now in the process of working with three states, Minnesota, Wisconsin and Michigan, in working out -- basically we're piloting in those three states. We have some draft memoranda of understanding which was one of the recommendations specifically of this committee to do that.

So, you know, just basically wanted to close the loop on that and to let you know we appreciated, you know, the committee's input.

The other thing that I want to bring up is just internally for us to do some QC and QA and especially, I think, to ensure consistency sort of across the board and to make sure that all the committee members, you know, have had the opportunity

for input and so forth.

My plan is to go back with the staff and sort of hammer out a survey that we will be polling all of you, okay, on our -- basically our procedures here as the full committee, our procedures in the subcommittee sessions and so forth, basically as I said, to ensure sort of consistency, smooth operation of the committee, and so that the agency is in fact getting the quality input that we know that we can get from this group.

So, staff doesn't know it but I have a meeting set up for 6:15 tomorrow morning, and we figure we -- no. No. But we'll go back and we'll hammer something out and so you should expect an e-mail from -- probably come from me or Sonya soliciting your input in this area and what other suggestions you have, so forth. We'll compile that and then hopefully come back, you know, and maybe have a conference call or something to talk about it, you know, rather than spending time at, you know, sort of everybody's precious time at a meeting here.

MR. MAJKOWSKI: I was just going to mention to the group, if you had comments about some of the things that we're doing or if you have some suggestions, some areas that we should be looking at, some other considerations, we'd appreciate it if you

can get them back to us within the next 60 to 90 days, the next two months. It would really be helpful because we're trying to move as quickly as we can on this, and we just don't want to delay it. So, we'd appreciate any comments or inputs that you would have.

Thanks.

MR. GIOGLIO: Linda, I don't have anything else, unless the committee has anything that you'd like to bring up at this time. I think it's been a long two days.

DR. JOHNSON: Charlie, thank you, you and your staff. Things went very well. The food was great.

MR. GIOGLIO: You like this place? I've heard that comment from a lot of people.

MS. SWACINA: We may have to pass the tin cup to do it again.

MR. MAJKOWSKI: Are you using biosecurity money since I came and talked to you?

MS. SWACINA: There's a charge for your appearance, yes.

MR. GIOGLIO: I think a lot of folks within the agency like this place, also, and, you know, I guess we had had the -- one of the scientific conferences just a few weeks ago here at this facility,

also. So, I'm looking to Jeanne because she controls the procurement office and so forth. So, we'll have to see what we can work out.

That's all I have.

Public Comment, Wrap-Up and Adjourn

MS. SWACINA: Okay. We do have public comment here on the list. No one signed up for it, but I thought I would just -- if there's any comments from the audience, this is the last final opportunity.

(No response)

MS. SWACINA: No? Okay. Okay. It looks like mostly FSIS people here.

All right. I do want to thank everyone from FSIS who participated and whether you're in the audience or whether you're up here. Your presence was appreciated and your knowledge and experience, and I do particularly also want to thank Charlie and his staff and you're right, the food was delicious. But you all made it run very smoothly. You all made the whole thing run very smoothly, and I appreciate that.

I certainly want to thank all of you on the committee. This is actually, I think, my first time to sit through the entire meeting, and I really learned a lot, and I appreciate all of your input. It really has been extremely helpful to me and to everyone else in

the agency, and we will take this back and we will proceed accordingly with your advice in mind.

With that, we are adjourned.

MS. ESKIN: Wait a minute. According to the agenda, we also have the opportunity at least just to talk about issues for our next meeting.

MS. SWACINA: I'm sorry. Sure.

MS. ESKIN: I'll start, if that's okay.

MS. SWACINA: Okay.

MS. ESKIN: Just a couple things. Based on the conversations we've had the last couple of days, in six months' time, which is our next meeting time, it would be useful to have some sort of an update on the status of HIMP, given that did generate a lot of discussion, if in fact you've gone forward with the third party review, whatever's happened. It would be useful because we did discuss that item.

MS. SWACINA: Right.

MS. ESKIN: We did touch a little bit on Listeria this afternoon, but to the degree there's anything to report, maybe the final rule will be out by then, but again my list just has very much pathogen-specific issues, whether it's Listeria, what is happening in terms of Campylobacter is obviously something that is also of concern.

I think an issue that we may have discussed last time and it's still out there, it's E.coli carcass testing, which is something I think we discussed. Again, these are all in order of maybe updates and if you have questions obviously that we can help you with, and also the status of any developments in terms of rapid testing of pathogens. I know there's some resources being used in terms of biosecurity. So, I think that would also be helpful.

Again, we talked about new technology. This is related in some way but this is very specific to the issue of rapid testing.

MS. SWACINA: Okay.

MS. ESKIN: That's my list.

MR. GIOGLIO: I guess what I would -- just in a quick response, and I'm glad you reminded me, we'll look for, you know, about the same time frame, around, you know, the early part of November for our next meeting.

Certainly the three issues that you raised would have been penciled in, I think, to the agenda of the next meeting anyway. So, we'll, you know, -- we appreciate your input.

MS. SWACINA: Does anyone else have issues they wanted to raise?

MS. BAYSE: You'll continually update us about biosecurity issues?

MR. GIOGLIO: Sure. Jesse has a standing invitation.

DR. JOHNSON: As long as he pays.

MS. AXTELL: This is a good way of examining head tax.

DR. JOHNSON: Charlie, I think it's also very good, you kind of gave us an update on what was going on with the recommendations on recall. I think maybe it would be good at the first of the meeting to have, okay, yeah, kind of an update, okay, here's where we are with this, this and this, to kind of follow through.

MS. ESKIN: Right, and some of the issues would require a very short discussion and some, like HIMP, may require a longer one, to get some continuity.

DR. MORSE: Nice to have an update on irradiation. A large grocery store in Western New York started irradiating its hamburgs. So, I'd be curious to know what's happening.

MS. SWACINA: In what sense?

DR. MORSE: I guess, is it being more widely accepted or are people using it? Customer acceptance.

MS. SWACINA: Okay. I would probably have to

change that a little bit because we don't really keep up totally with what the grocery stores are doing, but we do have this mandate as was discussed earlier in the Farm Bill about education on irradiation. So, as part of that, hopefully we'll find out some information that will be useful to you.

MS. KASTER: I wouldn't mind hearing an update on the dioxin residue testing that's being done and some of that sort of second part of the paragraph. As a large live production company with substantial feed supplies, we're pretty curious about where that's going to go, given the cost and the sampling methodology and that sort of thing.

MS. SWACINA: Well, so far, we have a weeklong meeting here, I think.

MS. KASTER: Maybe to make one quick point, because I think it ties in with the question that you're asking. In order to keep it from being a weeklong meeting, I really -- I liked, once I understood, the format that you went with, where we limited time of discussion on where maybe issues don't just drag on in discussion forever and everybody knows that you have X amount of time to put in your two cents' worth.

I'd rather see us talk about 20 issues

instead of five issues and have them for shorter periods of time. That's my personal preference.

MS. LEECH: Well, and if you know adequately in advance what they're going to be, you can prepare and maybe that will help.

MS. SWACINA: And again, we do apologize for the short notice on this one.

MS. ESKIN: I guess I would just want to respond that it would be nice to hit a lot of issues. However, if there are issues that require greater discussion because we all have questions or you all need some feedback from us, I hope we wouldn't be constrained if it was clear either before the fact when you're setting the schedule or in the process of the discussion, this has got a lot more to it than we thought, I hope we could have some flexibility, and it may mean meeting in subcommittee form or following up in some way at the next meeting.

MS. SWACINA: I think that this kind of discussion is perfect for what Charlie was talking about, too, about sort of issues, you know, sort of administrative issues of the committee. How do you want to operate? What kind of procedures do you want to put in place? I think that's a perfect topic for discussion of how you want to deal with that.

Okay? If I had a gavel, I'd bang it. So,  
thank you all very much.

ALL: Thank you.

(Whereupon, at 4:15 p.m., the meeting was  
adjourned.)

